ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA

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Submitted By

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DECLARATION BY THE CANDIDATE

I hereby declare that the thesis entitled "**ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA**" submitted towards partial fulfillment of the requirements for the award of **MS in GENERAL SURGERY** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Atul Mishra**, Professor, Department of General Surgery, **Dr. Saurabh Arora**, Former Associate Professor, Department of Endocrinology and **Dr. Amandeep Singh Nar,** Professor, Department of General Surgery. No part of this thesis has formed the basis for the award of any degree previously.

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Dedicated

to

my Parents

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“Do not go gentle into that good night; old age should burn and rave at close of day. Rage, rage against the dying of the light – Dylan Thomas”

First of all, I bow my head to the Almighty, who has blessed me with the strength to persevere through the struggles of life.

I’m highly indebted to my thesis guide, **Dr Atul Mishra, Professor, Department of General Surgery**, who owes everything about this project, from it’s inception to it’s completion. Without his guidance, such novel study could not have been even imagined. His thoughts and criticisms are what made this study possible.

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I thank my department for providing this opportunity and supporting me throughout the process.

Dr. Ravneet Singh Randhawa

LIST OF ABBREVIATIONS

AKI	Acute Kidney Injury
DM	Diabetes Mellitus
FHH	Familial hypocalciuric hypercalcemia
HPT	Hyperparathyroidism
ICG	Indocyanine green
IOPTH	Intraoperative Parathyroid hormone
MEN	Multiple Endocrine Neoplasia
MIP	Minimally Invasive Parathyroidectomy
PHPT	Primary hyperparathyroidism
PTH	Parathyroid hormone
RANKB	Receptor activator of nuclear factor k
RANKBL	Receptor activator of nuclear factor k ligand
TEP	Transaxillary endoscopic parathyroidectomy
TOEPVA	Trans Oral Endoscopic Parathyroidectomy Vestibular Approach

ABSTRACT

Introduction: Primary hyperparathyroidism (PHPT) is a common endocrine disorder characterized by excessive secretion of parathyroid hormone by adenoma, leading to hypercalcemia and associated complications. Traditional surgical approaches for parathyroidectomy, such as open parathyroidectomy , often result in visible scarring and longer recovery times. This study investigates the efficacy and safety of transaxillary endoscopic parathyroidectomy (TEP) as a minimally invasive alternative for the treatment of PHPT.

Through a prospective and retrospective analysis, we assessed various parameters including intraoperative complications, postoperative recovery, any failure or recurrence. Additionally, patient satisfaction and cosmetic results were evaluated.

The findings Indicate that TEP offers a viable and effective approach for managing PHPT, with significant advantages in terms of reduced postoperative pain, minimal scarring, and quicker return to normal activities. Complication rates were low, suggesting that TEP can be a safe alternative when performed by experienced surgeons. This study supports the integration of TEP into clinical practice as a standard option for patients requiring parathyroidectomy, emphasizing the importance of surgical expertise and patient selection in optimizing outcomes.

Aim of Study: To evaluate trans axillary endoscopic parathyroidectomy as an option for primary hyperparathyroidism secondary to parathyroid adenoma.

Materials & methods: A retrospective and prospective study of patients with primary hyperparathyroidism, undergoing trans axillary parathyroidectomy in the department of General Surgery, Dayanand medical college and hospital, over a period of three year.

Results: The transaxillary endoscopic parathyroidectomy (TEP) has demonstrated successful results in the treatment of primary hyperparathyroidism (PHPT). This minimally invasive technique has been associated with high cure rates, achieving normalization of serum calcium and parathyroid hormone levels in all of our patients. When performed by experienced surgeon, it is associated with a very low complication rate. Patients experience superior cosmesis owing to the hidden axillary scar,shorter hospital stay, often returning to normal activities within a few days. Follow-ups indicate sustained improvements in quality of life and minimal recurrence rates, affirming TEP as an effective and aesthetically favorable surgical option for managing PHPT.

Conclusion: Transaxillary endoscopic parathyroidectomy offers a valuable alternative to traditional cervical parathyroidectomy, particularly for patients who prioritize cosmetic outcomes and rapid recovery. While it presents certain technical challenges and requires specialized training, the benefits in terms of reduced postoperative pain, minimal scarring, and effective management of PHPT make it a compelling option. As surgical techniques and expertise continue to advance, TEP has the potential to become more widely adopted, providing patients with an effective and aesthetically favorable treatment for primary hyperparathyroidism.

Keywords: Transaxillary endoscopic parathyroidectomy, Primary hyperparathyroidism, Adenoma.

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INTRODUCTION

Primary hyperparathyroidism (PHPT) is one of the commonest endocrinologic disorder. It's incidence is 1/500 females and 1/2000 males, with post-menopausal women in the age group of 50-60 being involved more commonly[1]. PHPT occurs when one of the parathyroid glands enlarge and secrete PTH inappropriate to serum calcium levels. Parathyroid adenoma remains the most common cause for primary hyperparathyroidism; this is usually a single adenoma, but rare cases can have more than one adenoma [2]. Surgery is the only treatment for primary hyperparathyroidism. Bilateral exploration of parathyroid glands, called "Comprehensive parathyroidectomy" was the standard approach in the past. Since PHPT is caused by enlargement of a single gland; in such a scenario, performing Comprehensive parathyroidectomy is excessive. There have been many modifications in the surgical approach for PHPT. Advancements in endocrinology, radiology, and physiology have led to the introduction of radionuclide scans and intraoperative parathyroid hormone (IOPTH) monitoring. These innovations enable precise localization of diseased parathyroid glands both preoperatively and intraoperatively, enhancing the accuracy and effectiveness of surgical interventions. Currently, what is followed worldwide is focussed exploration of parathyroids[3].

Global advancements in surgical techniques, particularly those focused on minimizing incisions, have also influenced parathyroid surgery. This progress is embodied in the concept of "Minimally Invasive Parathyroid Surgery" (MIPS). Presently, the consensus within the medical community defines MIPS as involving an incision size of 2.5 cm or less[4].

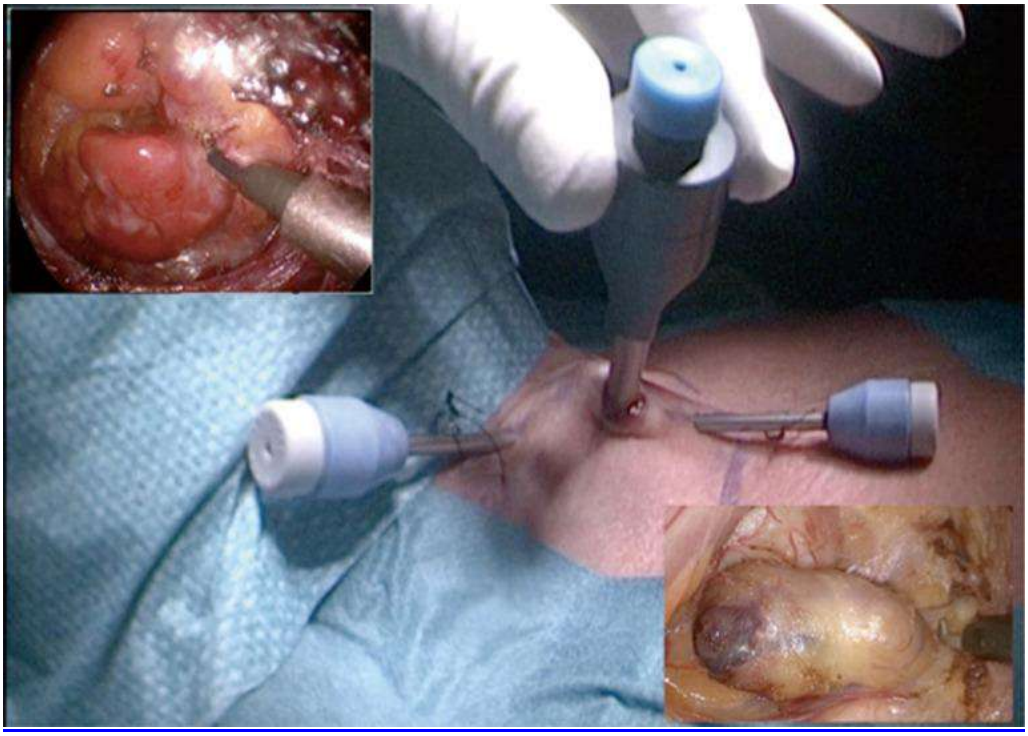
The integration of camera systems into various surgical procedures has significantly transformed the field, and endocrinological surgery is no exception. The advent of endoscopic parathyroidectomy exemplifies this progress. The use of an endoscope in parathyroidectomy offers substantial benefits, including superior illumination, enhanced visualization, and increased magnification. These advantages facilitate

a clearer anatomical view, allowing surgeons to delineate structures with greater precision.

Endoscopic parathyroidectomy was pioneered by Gagner et al., employing a three-trocar technique[5]. However, this approach proved insufficient for accessing posteriorly located parathyroid adenomas [6]. Subsequently, Henry et al. refined this method by developing the lateral approach, which allowed better access to posteriorly located adenomas[7-8]. This modified technique also used three trocars, strategically placed along the anterior border of the sternocleidomastoid muscle, and utilized a 0° endoscope for improved visualization[9].

Gagner's technique used two or three extra trocars and a central trocar to implant a 5 mm endoscope under a constant gas flow.[5]. As with open approach, sub-platysmal dissection was performed. After removing the thyroid from the fascia, the midline was exposed and the strap muscles were drawn back to reveal the thyroid lobe and investigate the parathyroid glands[10].

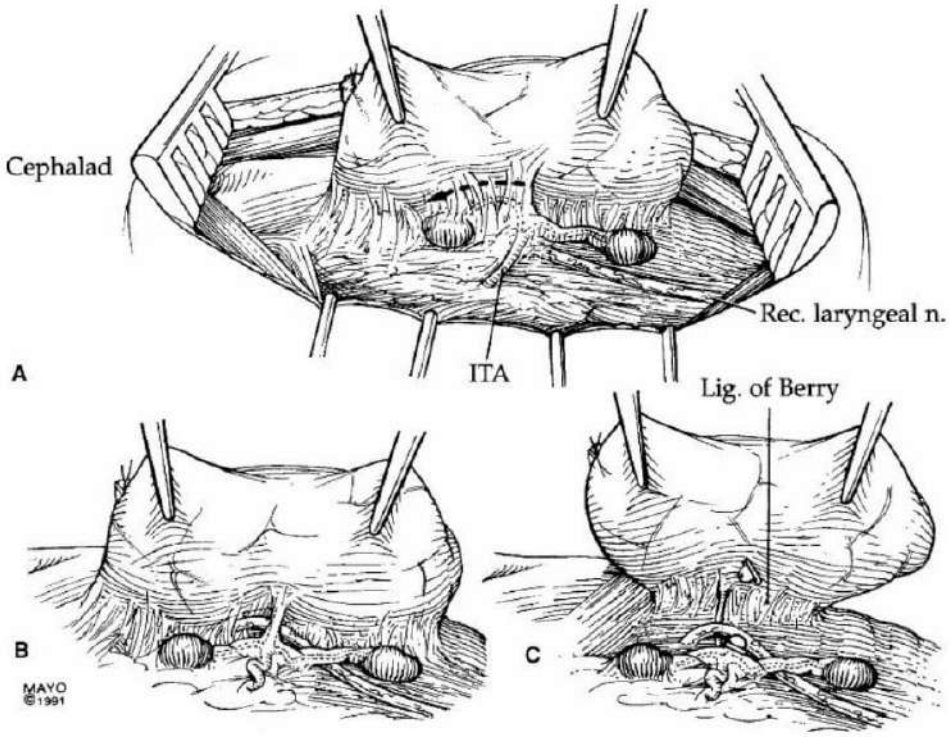
In Henry's technique, port is placed at the anterior margin of sternocleidomastoid. A 5-mm trocar with a 0° endoscope is inserted into the original incision, which is temporarily closed with a purse-string suture. Two 3-mm trocars are introduced cranially and caudally to the incision along the anterior sternocleidomastoid muscle boundary. The artificial space is expanded by insufflating carbon dioxide at a pressure of 8 mmHg, and dissection is carried out using 3-mm instruments. Identification of the ipsilateral parathyroid and the recurrent laryngeal nerve is frequently achievable during the surgery.



Picture 1: Conventional endoscopic parathyroidectomy using totally endoscopic lateral approach described by Henry et al. (1999).[11]

Embryology

The parathyroid glands develop from III and IV branchial pouches, with pouch III giving rise to inferior parathyroids and pouch IV giving origin to superior parathyroid. During their descent, the superior parathyroid glands have to travel lesser distance than inferior parathyroids. Due to their longer descent, the inferior parathyroid glands are particularly susceptible to being located in aberrant positions.



[12]

Picture 2: Anatomy of Parathyroid glands

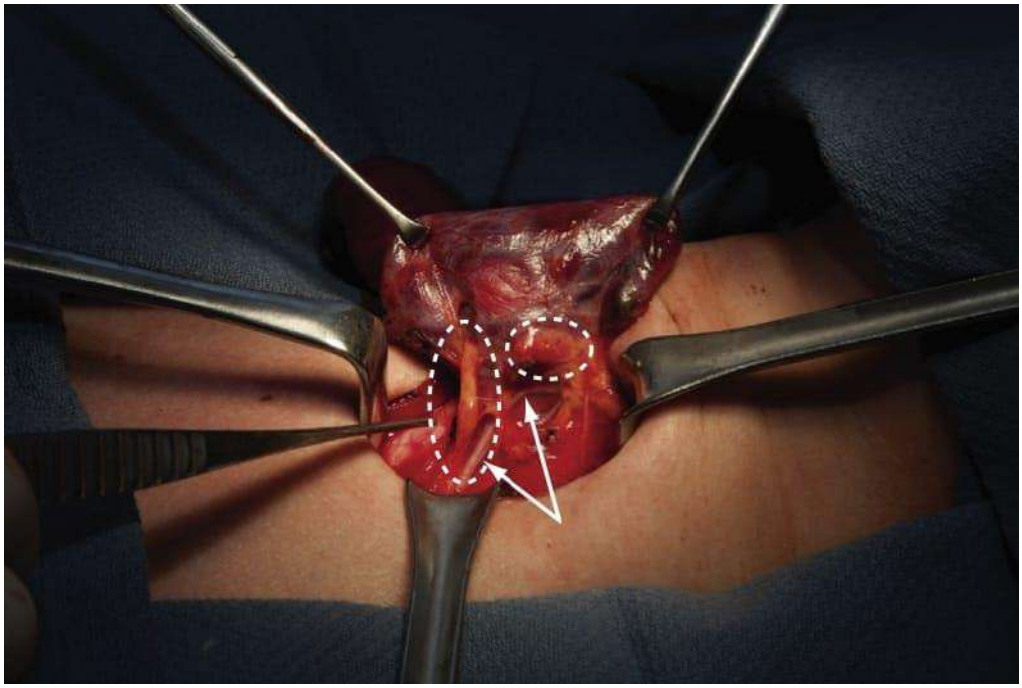
Anatomy and Physiology

Parathyroids are four glands located in posterior relation to the thyroid, with usual weight in the range of 30 to 50 mg. The two superior parathyroid glands are classically located posterior to the recurrent laryngeal nerve. As compared to the inferior parathyroid glands, they have a more constant location. The two inferior parathyroid glands are classically located inferior to the thyroid and anterior to the plane of the recurrent laryngeal nerve, but sometimes can be located in very aberrant locations in the lower neck, in the parenchyma of the thyroid gland or thymus remnant, in the carotid sheath, the retro-oesophageal space, or the mediastinum. There can also exist true ectopic glands; 16% patients with PHPT will have parathyroid gland in an ectopic location [13]. These may also be located in the carotid sheath, paraesophageal or retro-oesophageal space, or intrathyroidal or mediastinal positions. In 13% population, we can have extra parathyroid glands, called “Supernumerary glands”[14] ; only 50% of these supernumerary glands are proper glands, rest are just collections

of parathyroid tissue that are functionally insignificant. Supernumerary glands become surgically important in following scenarios –

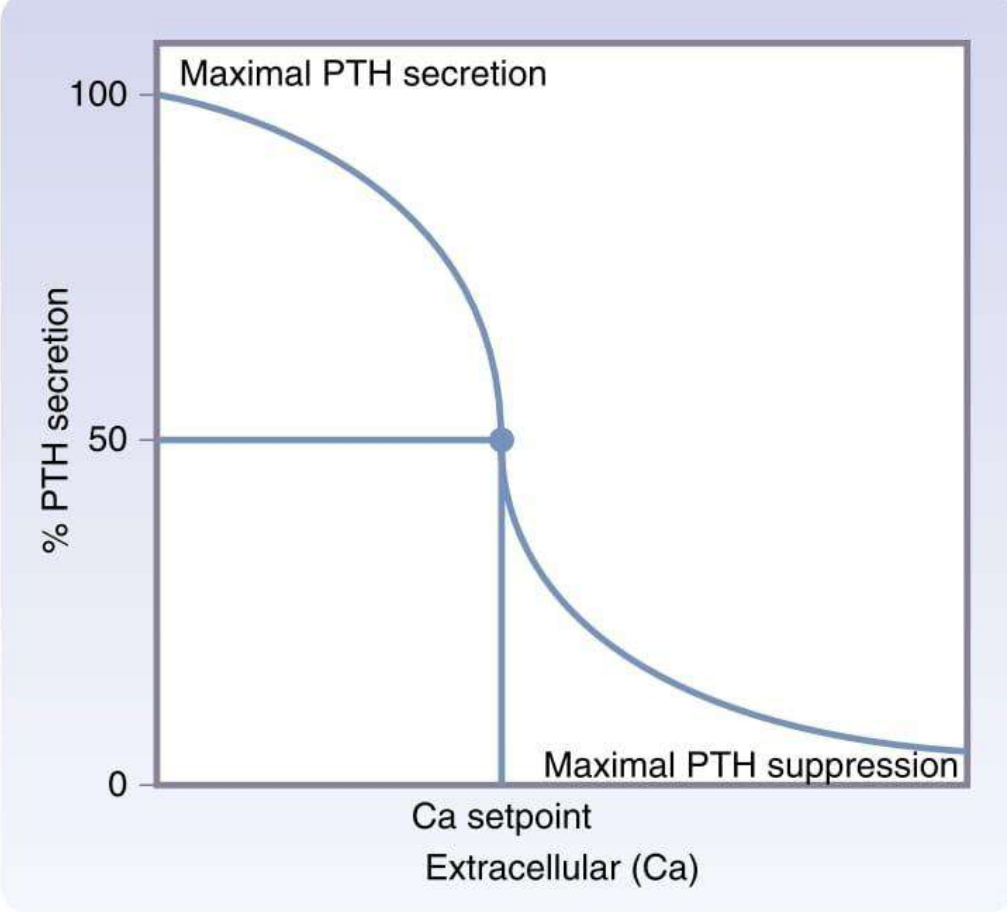
1. MEN1 associated HPT
2. Secondary HPT due to renal disease, in which all glands are stimulated
3. HPT due to hyperfunctioning supernumerary gland
4. Double adenoma – adenoma arising from both normal and supernumerary gland

The inferior thyroid artery from the thyrocervical trunk supplies the four parathyroid glands. 20% of people have their superior parathyroid glands deriving its blood supply from superior thyroid artery or, more commonly, by an anastomotic branch between the inferior thyroid and the superior thyroid artery.[15]



Picture 3: Intraoperative appearance of parathyroid glands.[16,17]

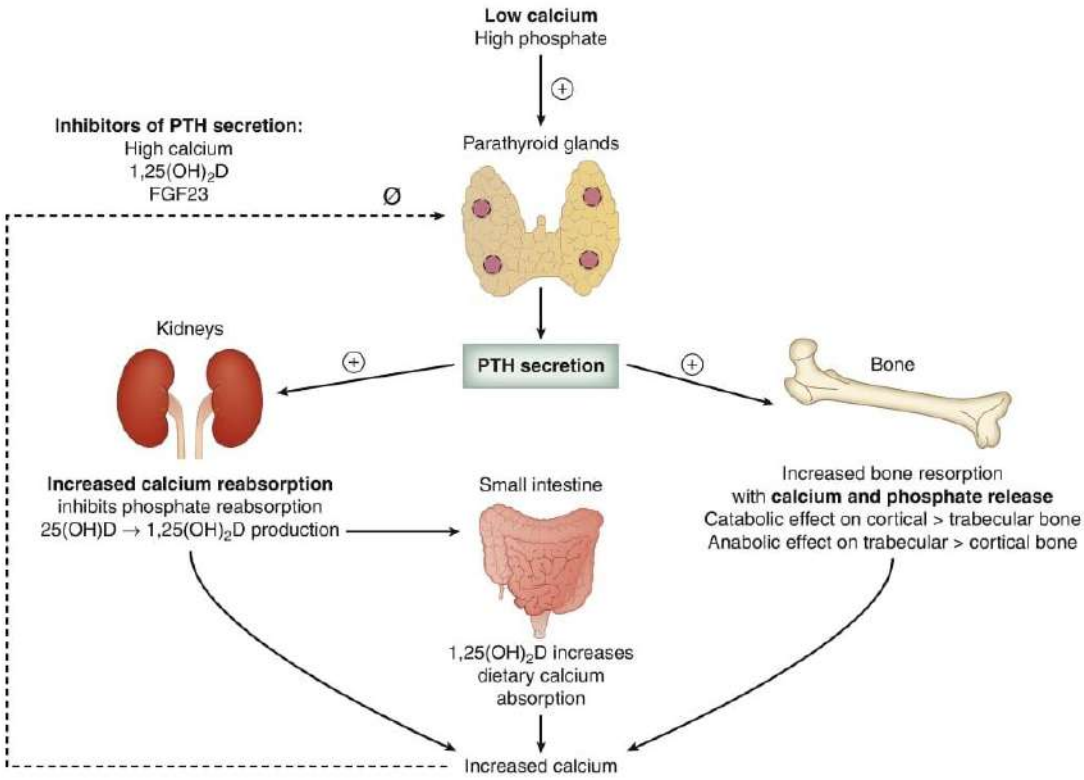
Synthesis and secretion of PTH is predominantly controlled by levels of extracellular calcium, with maximum PTH secretion occurring at low calcium levels and maximal suppression occurring at high calcium levels.



Picture 4: Correlation between levels of parathyroid hormone and serum calcium [18]

Parathyroid glands regulate calcium by secreting parathyroid hormone (PTH). With a fall in serum calcium levels, the chief cells in the parathyroid release PTH. PTH has renal action of increasing calcium reabsorption in the loop of Henle (as well as in the distal tubule and collecting duct), excretion of phosphate, and promotes 25-hydroxy vitamin D converting to active 1,25-dihydroxy vitamin D3. In bone, PTH exerts anabolic and catabolic effects; PTH receptors are found on cells of osteoblastic lineage, through which this hormone stimulates formation of new bone matrix and mineralization of bone. Following factors are produced by cells of osteoblast lineage, for regulation of osteoclast formation – receptor activator of nuclear factor kB (RANKB), osteoprotegerin(OPG), and receptor activator of nuclear factor kB ligand(RANKBL). PTH stimulates release of OPG and RANKBL, thereby leading to bone resorption and release of mineral component

of bone. The net effect of PTH on bone, however, is determined by chronicity of PTH excess. [19], with patients of secondary and tertiary hyperparathyroidism having osteopenia and osteoporosis. Studies have concluded that when given intermittently, PTH stimulates bone formation. This finding led to the introduction of novel therapies like intermittent PTH administration for treatment of osteoporosis. [20]. In the intestine, activated Vitamin D increases the absorption of calcium.



Picture 5: Actions of PTH on end organs [18]

Hyperparathyroidism is a disorder with excessive synthesis of PTH due to the overactivity of the parathyroid gland(s). Primary hyperparathyroidism results from autonomous hypersecretion of PTH from the abnormal parathyroid gland. Maximum of patients with primary hyperparathyroidism have a single enlarged parathyroid gland, usually an adenoma, though hypercellular parathyroid is also possible. Up to 10% of patients with primary hyperparathyroidism will have two abnormal glands. Multiple endocrine neoplasia (MEN) type 1, type 2A, or parathyroid carcinoma can cause primary hyperparathyroidism in rare cases. The high calcium level due to hypersecretion of PTH can lead to neuromuscular symptoms, osteoporosis bone loss, and kidney

stones. Secondary hyperparathyroidism is due to high PTH levels from the physiological response to hypocalcemia. The most common causes of secondary hyperparathyroidism are Vitamin D deficiency and chronic renal failure. Tertiary hyperparathyroidism occurs in patients with secondary hyperparathyroidism from chronic renal failure and persistent secretion of PTH after renal transplant. Apart from primary and tertiary HPT, all other causes of hypercalcemia are associated with low levels of PTH; exception to this is familial hypocalciuric hypercalcemia(FHH) and Lithium-induced HPT. In FHH, the renal CaSR are set at a higher set-point. It is a autosomal dominant disorder, and is characterized by hypocalciuria, asymptomatic hypercalcemia, and mildly elevated or normal PTH levels. Owing to its high penetrance, patients with FHH develop chronically elevated serum calcium levels, typically before the age of 30 years (in contrast to PHPT). Patients do not have any symptoms of PHPT. FHH does not warrant any treatment[21].

In parathyroid adenoma, the adenoma cells have a lower than normal sensitivity to inhibitory effects of calcium and a higher set point of calcium so that serum calcium levels remain at an elevated level; in hyperplasia, there is an overall increase in the number of cells but no change in sensitivity to calcium.[22]

Indications for parathyroidectomy in PHPT –

I. All symptomatic patients
II. Serum calcium >1mg/dl above normal
III. BMD(Bone mineral density) T score <-2.5(i.e. osteoporosis) or significant reduction in BMD
IV. Vertebral compression fracture on spine imaging
V. Renal failure – GFR <60 ml/min
VI. Nephrolithiasis or nephrocalcinosis
VII. Hypercalciuria

Patients with age less than 50 years of age and do not wish to get operated for PHPT are more likely to develop complications[23,24] .

Localization of parathyroids – USG neck and Sestamibi scan are the imaging modalities commonly used for localization of parathyroids, with USG neck being the most common initial imaging modality.

USG neck – on ultrasound, abnormal parathyroid will be visualized as a round or oval hypoechoic mass with hypervascular echogenic capsule. USG has drawbacks of being a user-dependent modality, detecting ectopic parathyroids, difficulty to differentiate between lymph node, parathyroid adenoma and thyroid nodule. A recent meta-analysis has established a sensitivity of 76%; its sensitivity for detecting multi-gland disease is even lesser(35%).[25]

Sestamibi scan – this imaging is dependent on the differential uptake and retention of the radiotracer Sestamibi in the mitochondria rich cells of tissues that are metabolically hyper-active(i.e. parathyroid cells). Two ways of performing this are with a dual-phase technique using a single isotope or a single phase technique using dual isotopes; SPECT(single photon emission CT) can be combined to both of these techniques. SPECT adds the element of “3D” and improves localization of pathological parathyroid, while CT adds further details to anatomy[26]

Dynamic four-dimensional CT(4D-CT) – the “four” dimensions refer to –

I. Non contrast phase
II. Early arterial phase – 45 seconds after injection of IV contrast
III. Delayed arterial phase – 75 seconds after injection of IV contrast
IV. Assessment of change in perfusion over time

When compared to thyroid tissue, parathyroid tissue will show the following changes –

I. Non contrast phase – it has a lower attenuation(45 HU) as compared to thyroid tissue(90 HU)
II. Early arterial phase – rapid enhancement; maximum achievable attenuation is 130 HU
III. Delayed phase – rapid washout.

It is particularly useful for small adenomas and in localizing the abnormal gland in reoperative cases.

Intraoperative adjuncts – Intra op PTH monitoring

It helps confirm that all pathologic parathyroid tissue has been removed. Blood is drawn from a peripheral line at specific time intervals during surgery, based on which protocol is followed. PTH has half-life of 3-5 mins, and once the involved gland is excised, levels are destined to fall. Following time-stamps have been created for drawing PTH levels during surgery.

I. Preincision – at a date prior to surgery or prior to starting the procedure on day of surgery
II. Pre-excision – after exposing an abnormal gland but prior to ligating its blood supply
III. 5-min after removal of gland
IV. 10-mins after removal of gland

Two types of criteria are followed worldwide – Miami criteria and Dual criteria.

Miami criteria – there should be a >50% decline in PTH levels at 10 mins post excision as compared to the highest pre-op baseline, to confirm that the correct gland has been removed.

Dual criteria – there should be >50% fall in PTH levels from the pre-incision level, along with a final PTH that is within normal range.

These two criteria have an accuracy rate of 97-99%.[27,28].

Frozen section – this gives us a histological diagnosis which provides the confirmation that parathyroid tissue has been removed. Secondly, it also helps differentiate between adenoma and hyperplasia. [29,30]

Indocyanine green – it helps in localization of parathyroid adenoma because it gets accumulated in pathological parathyroid. ICG fluoresces at about 800 nm. In case of an adenoma, there will be increased signal intensity. [31-33]

AIMS AND OBJECTIVES

To evaluate role of transaxillary endoscopic parathyroidectomy for primary hyperparathyroidism secondary to parathyroid adenoma

Zheng et al., (2023) This study aimed to evaluate trans-axillary parathyroidectomy as a treatment option for parathyroid adenoma. This was a retrospective study, which evaluated 41 patients (37 women and 4 men) who underwent trans-axillary parathyroidectomy over the period of 2 years. Success was calculated in terms of drop in PTH and serum calcium levels. All patients had accurate localization and removal of adenoma. The study concluded that trans-axillary endoscopic parathyroidectomy is a safe treatment option for people with PHPT.[34]

Zhang et al., (2022) They compared trans-axillary endoscopic parathyroidectomy with open parathyroidectomy. This study was done over a period of 39 months. It consisted of 26 patients (12 in endoscopic group vs 14 in open group). More proportion of young patients opted for endoscopic approach. Following parameters had a statistically insignificant difference – operative time, intra-op blood loss, hospital stay and surgical efficiency. Patients in the open group had more significant neck pain. Neither group had injury to RLN or post-op blood loss. During follow up, 1 patient in open group and none in endoscopic group developed recurrence. This study concluded that trans-axillary endoscopic parathyroidectomy has good surgical efficacy and outcomes.[35]

Bhandarwar et al., (2021) Their study compared trans-axillary endoscopic approach with trans-vestibular approach. It included 27 patients (16 in trans-axillary group vs 11 in trans-vestibular group). Exclusion criteria – previous history of neck surgery, history of neck irradiation, enlarged thyroid. When compared, mean operative time was 47 minutes in trans-axillary group and 104 minutes in trans-vestibular group. Mean blood loss was 68 ml in trans-axillary group vs 34 ml in trans-vestibular group. A single patient from trans-vestibular group required conversion to open because of unsatisfactory fall in intra-op PTH levels. One patient had transient RLN palsy, which was

managed conservatively. Conclusion – in appropriately selected candidates, endoscopic parathyroidectomy is an efficacious alternative to open parathyroidectomy.[36]

Saito et al., (2021) Their study evaluated transaxillary endoscopic parathyroidectomy with open parathyroidectomy. Time period of their study was 4 years and in total, 28 patients were included. 11 patients(10 females and 1 male) were in the transaxillary endoscopic parathyroidectomy group and 17(11 females, 6 males) were in the open parathyroidectomy group. As compared to open parathyroidectomy, transaxillary endoscopic approach was opted by comparatively young patients(mean age 54 years vis-à-vis 63 years), had a longer operative time, but lesser complications(RLN injury, seroma formation). This study concluded that trans-axillary approach is superior to open parathyroidectomy in terms of complication rate and cosmetics. [37]

Burhan Mayir et al, 2021 – they performed endoscopic parathyroidectomy via unilateral axillo-breast approach. Their study was composed of 3 patients(two females, one male). Patients were aged in the range of 24-67 years, with the mean age being 47.3 years. For localization of adenoma, USG neck and Sestamibi scan were used. All cases concluded by endoscopic approach, with the mean operative time being 147 mins. Normalization of serum calcium levels and serum PTH levels was achieved on POD1 in all patients, when all of them were discharged.[38]

Kandil et al, 2021 – they conducted a retrospective study on Robot assisted parathyroidectomy for treating PHPT. This study extended from the period of July 2010 to July 2019. Two institutes, in two countries(USA and France) were chosen for this. This study had a sample size of 102; 80% of patients were females, 20% were males. Median age for their patient population was 55.6 years. Median BMI of their patients was 25.5 kg/m^2 .Mean operative time was calculated to be 116 mins. 101 cases proceeded entirely with trans-axillary

approach; one patient requiring conversion to open. What their study find out was that an experienced surgeon can gain proficiency in Robotic trans-axillary parathyroidectomy in less than 15 cases; one of their surgeons gained proficiency after performing 8 cases, the other one by fourteenth case. Their results, however, cannot be generalised, because the population studied here was Western.[39]

Paspala et al,2021 - They analysed studies on Robot-assisted parathyroidectomy, performed during a 19 year period from January 2000 to September 2019. Aim of their study was to analyse short-term outcomes in patients who underwent this form of parathyroidectomy. In total, 64 patients were studied, 21% were males and 79% were females. Amongst them, different patients underwent different approach of robotic parathyroidectomy; 79.6% cases(51 out of 64) underwent trans-axillary approach, 9.3%(6 out of 64) patients underwent trans-oral and bilateral axillo-breast approach each. 1.5% patients underwent retro-auricular approach. Adenoma was removed in all patients. 9.2% patients developed complications, with most common being seroma formation, which was managed conservatively. None of the patients had nerve injury. Eucalcemia was achieved in 89% patients. All patients had satisfaction with the cosmesis. 3.5% patients were discharged on the same day, and 82.4% on POD1. None of the patients developed recurrence. This study proved that robot-assisted parathyroidectomy gives good result in terms of outcome, cosmesis, hospital stay.[40]

Lee et al,2023 – they conducted a retrospective study over a period of 10 years, from December 2013 to August 2023. Aim of their study was to prove robotic trans-axillary parathyroidectomy as a treatment option for PHPT. Their study included a total of 12 patients, of which 11 were females and 1 was male. Median age of their patient's was 44.5 years. Another variable which they took into account was tumor localization; 5 patients had adenoma of left superior parathyroid, 4 had adenoma of right inferior parathyroid, 3 had adenoma of left inferior parathyroid.

Mean operative time of their approach was 113 minutes. Complications like post-operative bleeding was seen only in one patient. Two patients had high post-operative PTH levels, 2 weeks after surgery; one of these patients had persistently high PTH even after 15 months of surgery, but overall, PTH levels were on falling trend. Normocalcemia was achieved in all. None of the patients had any recurrence or failure of surgery. Their study concluded that Robotic trans-axillary parathyroidectomy is a viable treatment option for PHPT.[41]

Sabuneuglu et al,2024 – they conducted a retrospective study from a single centre in Turkey, comparing Transoral Endoscopic Parathyroidectomy Vestibular Approach (TOEPVA) vs Open parathyroidectomy. Their study was non-randomized, controlled study. Total number of patients in their study was 57, of which 20 patients were in TOEPVA group and 37 in Open group. Variables studied were size of adenoma, localization of tumor, operative time, bleeding, RLN damage, any development of hypocalcemia. For TOEPVA, 3 incisions were given in lower lip; a midline incision for 10mm port, through which 30^0 camera was inserted. This port was inserted above frenulum. The other two ports were two 5-mm ports, inserted on lateral aspect of canines; these were working ports. When compared with Open parathyroidectomy, no significant difference was noticed in the mean age of patients opting for TOEPVA or Open parathyroidectomy(49.9 years vs 57.2 years; p - 0.291). All patients in TOEPVA group were females, while open group had 83% females. When all other variables were analysed, it was concluded that there is no significant difference in TOEPVA vs open parathyroidectomy.[42]

Uludağ et al., (2019) Conducted a study to the only curative treatment for primary hyperparathyroidism (pHPT) is surgery. There are various surgical techniques to treat HPT; however, 2 main surgical options are used: bilateral neck exploration (BNE) and minimally invasive parathyroidectomy (MIP). While there are open, endoscopic, and video-assisted MIP (MIVAP) approaches, most often an open lateral

MIP technique is used. In addition, endoscopic or robotic parathyroidectomy methods performed from remote regions outside the neck have been reported. Although currently MIP is the standard treatment option in selected patients with positive imaging, BNE remains the gold standard procedure in parathyroid surgery. In 80% to 90% of patients with pHPT, a pathological parathyroid gland can be detected with preoperative imaging methods and MIP can be applied. However, the pathological gland may not be found during a MIP procedure as a result of false positive results. The parathyroid surgeon must also know the BNE technique and be able to switch to BNE and change the surgical strategy if necessary. If the intended gland is not found in its normal anatomical site, possible embryological and acquired ectopic locations should be investigated. What we need to note is that MIP and BNE are not alternatives to each other, but rather complementary techniques for successful treatment in parathyroid surgery.[43]

Arora et al., (2018) explained that Robotic parathyroidectomy represents a novel approach for the treatment of primary hyperparathyroidism. It is the fourth generation in parathyroid surgery. The term "fourth generation" refers to the current state of parathyroid surgery, which has evolved from cervicotomy and 4-gland exploration to a range of targeted, open, and minimally invasive techniques. The existing evidence (levels 2–3) supports it as a feasible and safe technique with equivalent results to targeted open parathyroidectomy for primary hyperparathyroidism in carefully selected patients. However, it takes longer to perform and is more costly than conventional parathyroidectomy. It offers superior cosmesis by completely avoiding a neck scar making it a valid option for those patients who for biological and/or cultural reasons may wish to avoid a neck scar. Robotic parathyroidectomy is not for every patient, surgeon, or hospital. Its application should be confined to high-volume centres and experienced surgeons. Intensive training and proctorship are required for its safe implementation combined with careful patient selection. This particularly relates to the patient’s body habitus (BMI <

30 kg/m^2) and concordance among the different imaging modalities used pre-operatively. With robotic market competition driving down costs, its role may change. For now, robotic parathyroidectomy occupies a niche role and can only be justified in a select subset of patients.[44]

MATERIALS AND METHODS

Our study was retrospective and prospective study by design. It included 20 patients who underwent transaxillary endoscopic parathyroidectomy for PHPT secondary to parathyroid adenoma.

Source of data – it was a retrospective and prospective study that included 20 patients who underwent transaxillary endoscopic parathyroidectomy in the department of General Surgery, Dayanand Medical College and Hospital, Ludhiana, during a 3-year period.

Method of collection of data – all patients detected with parathyroid adenoma who were willing to undergo transaxillary endoscopic parathyroidectomy were included. After taking informed consent and eliciting detailed history, findings of physical examination, lab tests and imaging investigations were recorded.

Inclusion criteria – all patients diagnosed with PHPT undergoing trans-axillary endoscopic parathyroidectomy were included.

Exclusion criteria – patients who were not consenting for surgery.

Duration of study – 3 years

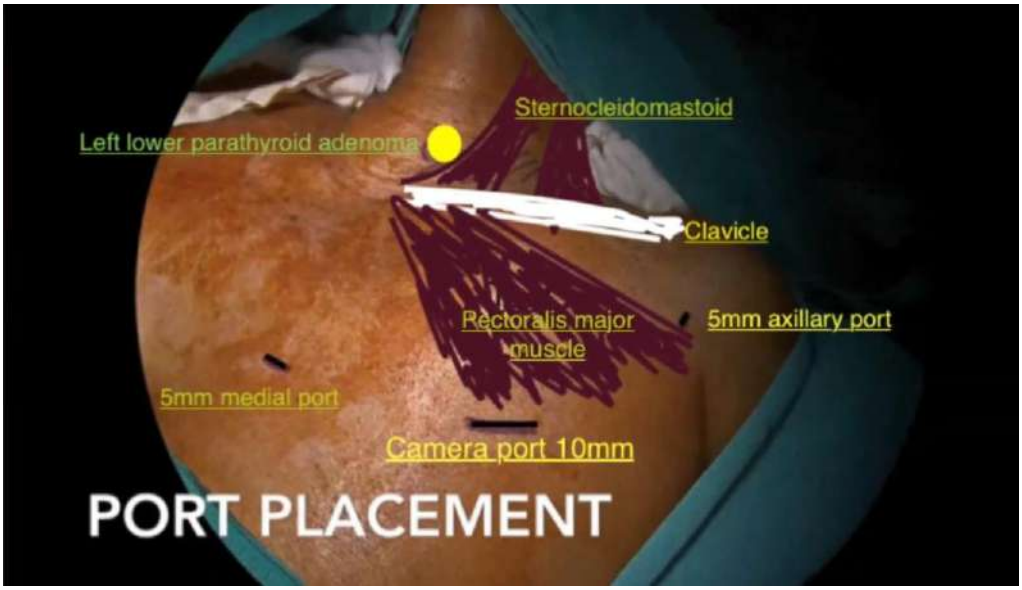
Number of cases – 20

Outcome – to evaluate the role of transaxillary endoscopic parathyroidectomy in primary hyperparathyroidism due to parathyroid adenoma.

Methodology – after obtaining informed consent from patients diagnosed to have primary hyperparathyroidism, we conducted our approach of transaxillary endoscopic parathyroidectomy.

Our approach of trans-axillary endoscopic parathyroidectomy

Port placement – we use a central 10mm port for camera and two other 5mm working ports, medially and laterally.

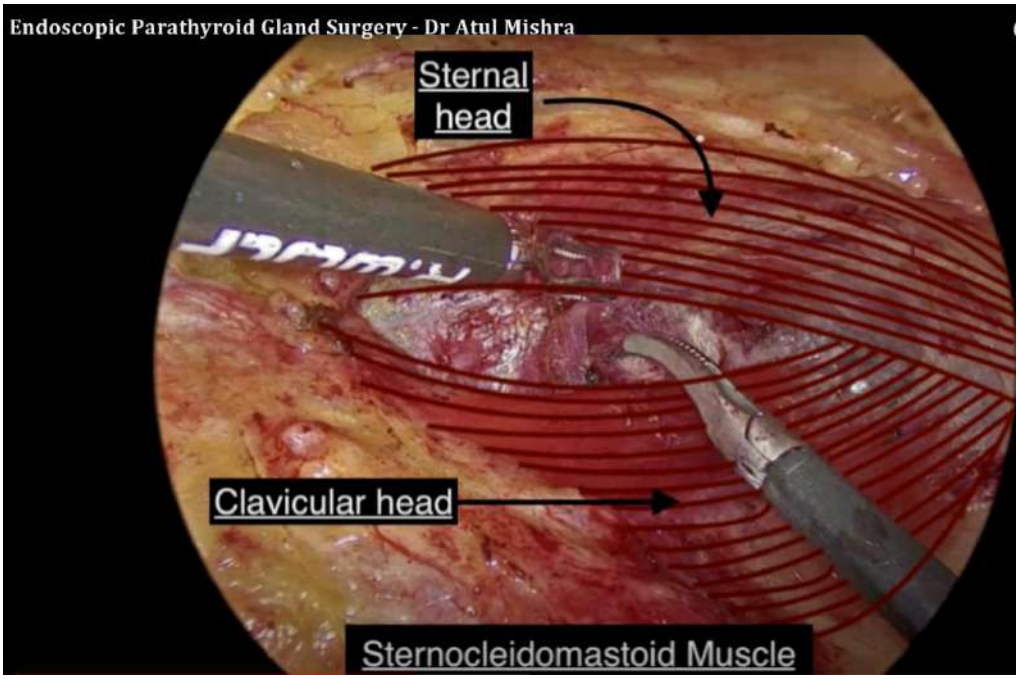


Picture 6: Port placement in transaxillary endoscopic parathyroidectomy

By finger dissection, we create a working space anterior to the pectoralis muscle. Clavipectoral fascia is then divided with an energy device and in this way, we enter the neck.

Picture 7: Division of clavipectoral fascia

Division is continued upto the space between sternal and clavicular head of sternocleidomastoid.

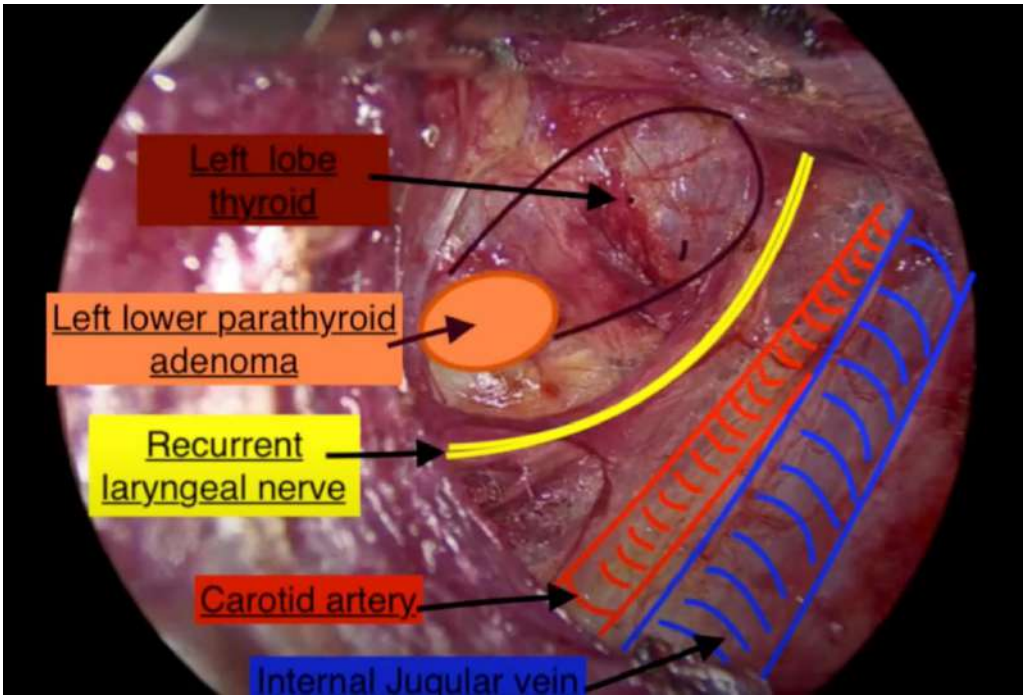


Picture 8: Space between clavicular and sternal head of sternocleidomastoid

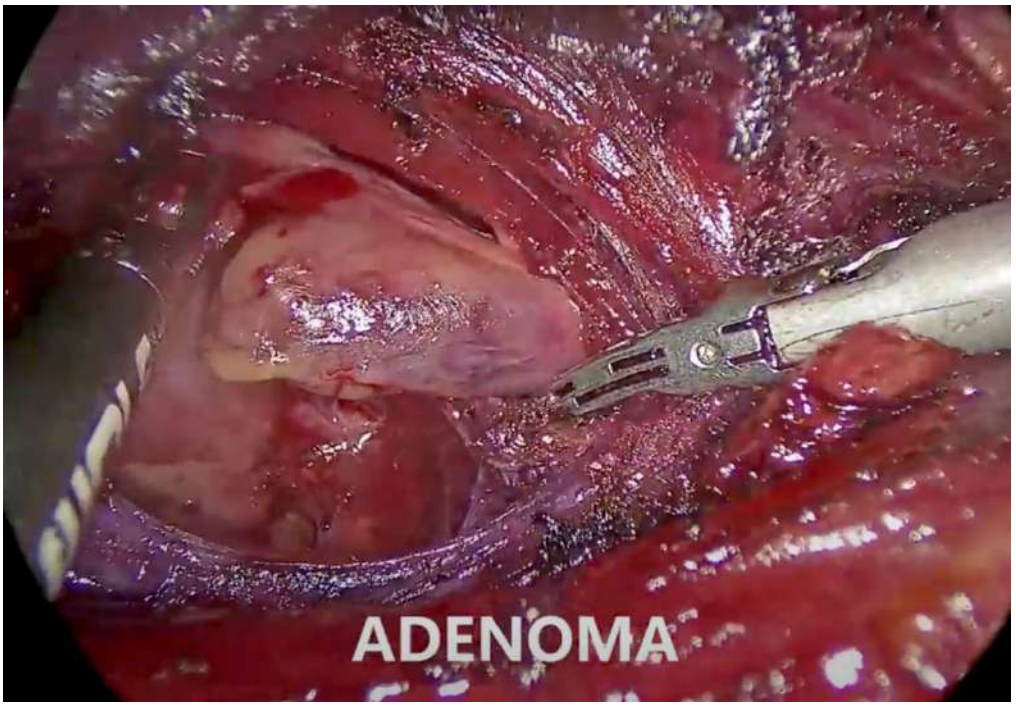
Upon reaching this space, we divide the investing layer of cervical fascia, and continue division till we reach deeper to the strap muscles.

Picture 9: Investing layer of deep cervical fascia

At this point, we will reach the plane of thyroid, and the parathyroids will be visualized.



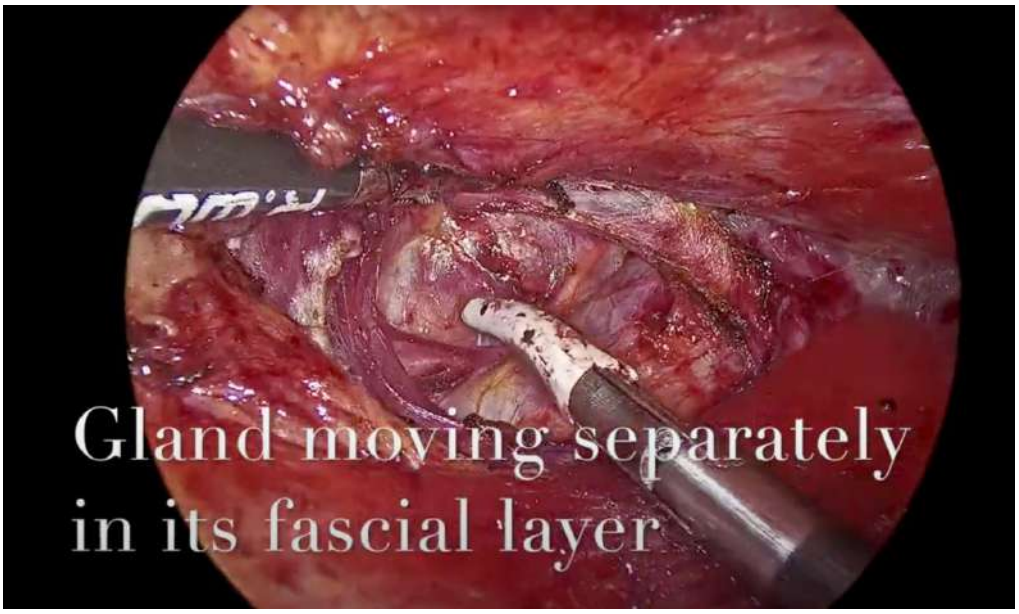
Picture 10: Structure related to parathyroid adenoma



Picture 11: Parathyroid adenoma

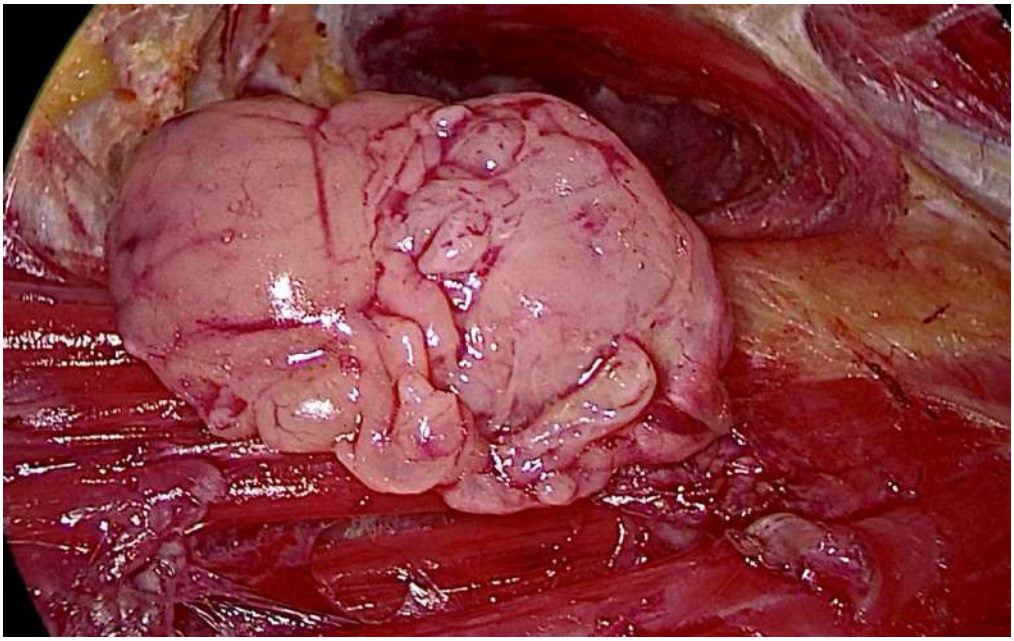
Points for intra-op detection of parathyroid adenoma –

I. Brownish color
II. Spider like vessels on surface
III. Gland moves separately in layers
IV. Soft and impalpable
V. Distinct encapsulated smooth surface
VI. Distinct hilar vessels



Picture 12: Parathyroid gland moving separately in its fascial layer

After excising the adenoma, we send serial PTH levels along with frozen section of parathyroid to confirm excision of parathyroid adenoma.



Picture 13: An excised Parathyroid Adenoma

Post op levels of serum calcium are monitored.

Statistical analysis – data will be described in terms of range; mean +/- standard deviation(SD), frequencies and relative frequencies(percentages) as appropriate. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

OBSERVATIONS AND RESULTS

Our study was conducted over a period of 3 years. It was a prospective and retrospective study. A total of 20 patients were included in the study.

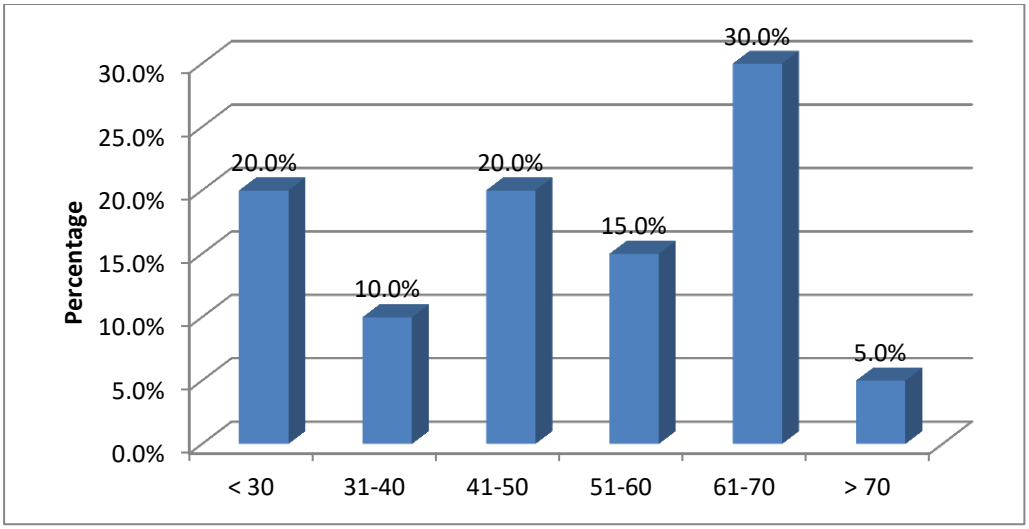
Age group

30% of patients were in the age group of 61-70 years, 20% in 41-50 years, 20% under 30 years, 15% in 51-60 years, 10% in 31-40 years and 1% above 70 years of age.

Table 1: Age group of patients

AGE	No. of cases	Percentage
< 30	4	20.0%
31-40	2	10.0%
41-50	4	20.0%
51-60	3	15.0%
61-70	6	30.0%
> 70	1	5.0%
Total	20	100.0%

Figure 1: Age group of patients



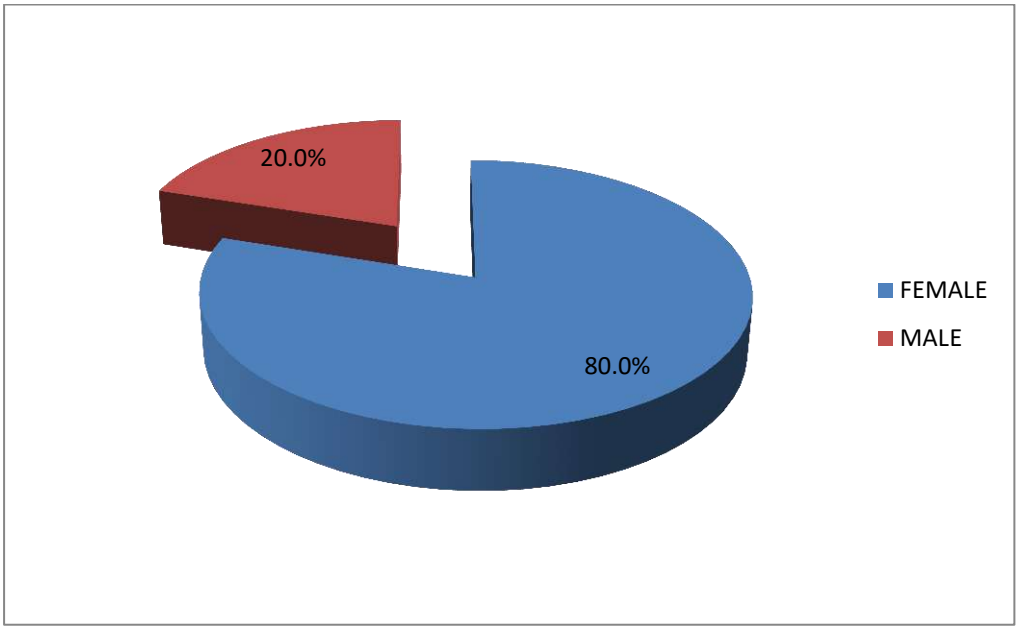
Gender

80% of patients were females and 20% were male.

Table 2: Gender distribution of patients

SEX	No. of cases	Percentage
FEMALE	16	80.0%
MALE	4	20.0%
Total	20	100.0%

Figure 2: Gender distribution of patients



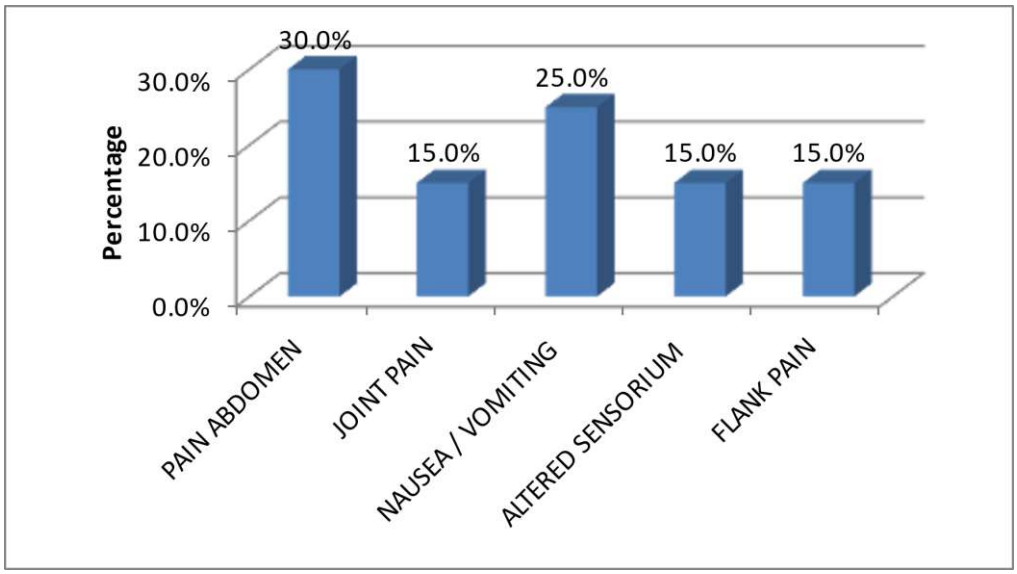
Presenting complaints

Pain abdomen was the chief complaint in 30% patients; in two of these patients, the pain had the following characteristic – present in epigastrium, radiating to back, associated with vomiting. Amylase and lipase levels were found to be elevated.In 25% patients, the presenting complaints were nausea, vomiting. 15% of patients had joint pains, 15% had disorientation on presentation, 15% had flank pains.

Table 3: Chief complaints of patients

CHIEF COMPLAINTS	No. of cases	Percentage
PAIN ABDOMEN	**6**	30.0%
JOINT PAIN	3	15.0%
NAUSEA / VOMITING	5	25.0%
ALTERED SENSORIUM	3	15.0%
FLANK PAIN	3	15.0%

Figure 3: Chief complaints of patients



Complications of hypercalcemia

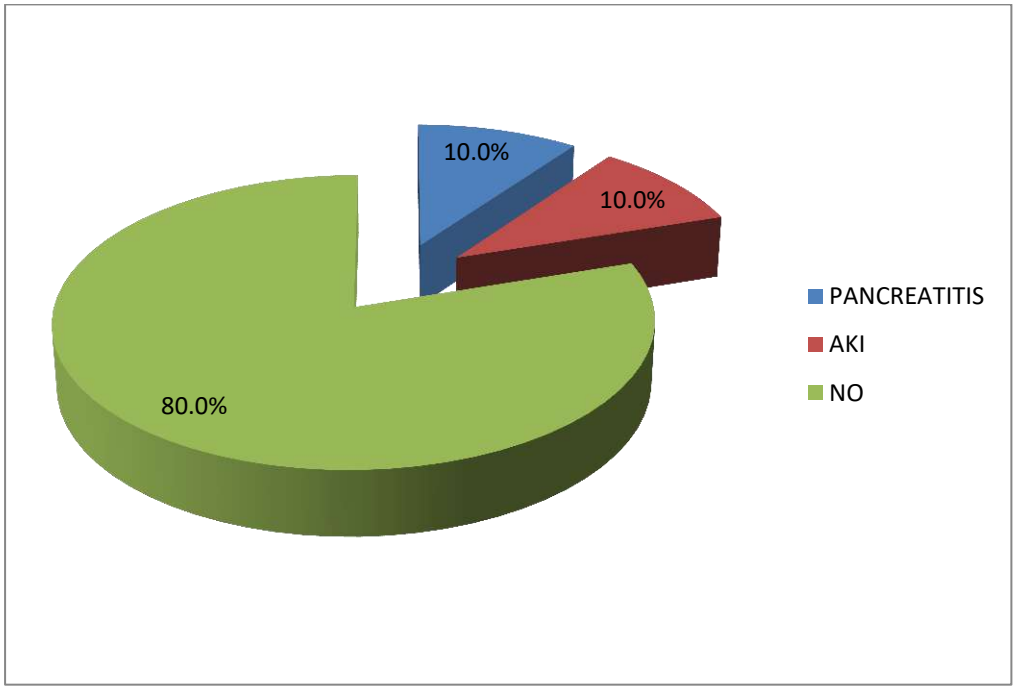
Pancreatitis - it was seen in 2 patients, who complained of epigastric pain radiating to back. Amylase and lipase were elevated, but these patients had mild pancreatitis. They were operated once pancreatitis resolved.

Acute kidney injury – 2 patients developed AKI mandating dialysis.

Table 4: Complication of hypercalcemia

COMPLICATION OF HYPERCALCEMIA	No. of cases	Percentage
PANCREATITIS	2	10.0%
AKI	2	10.0%
NO	16	80.0%

Figure 4: Complication of hypercalcemia



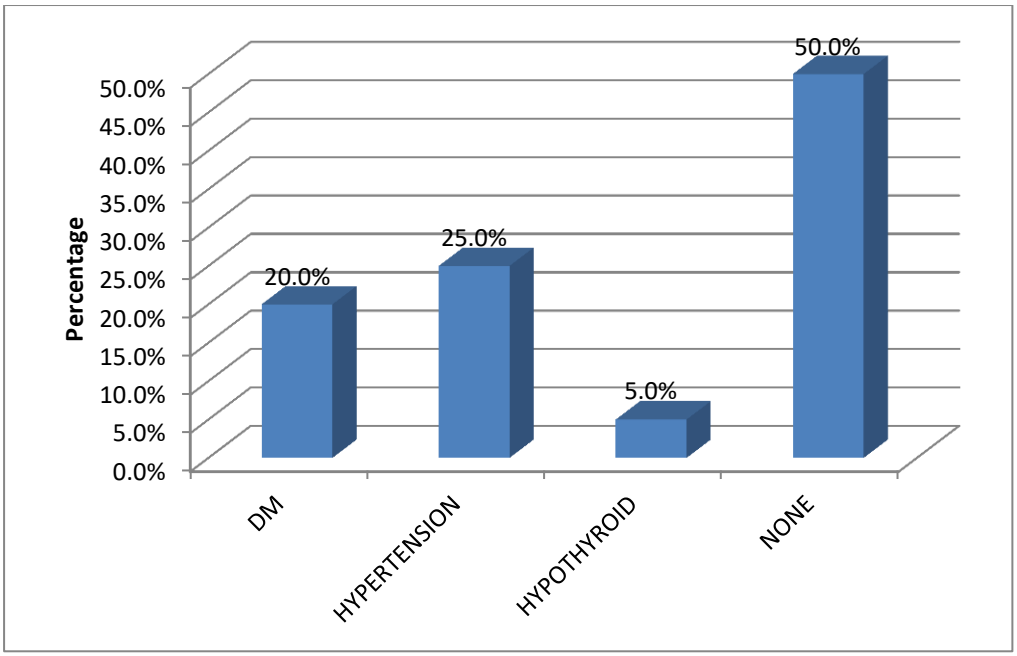
Comorbidities

50% patients had no comorbidity, 25% were hypertensive, 20% were diabetic and 5% were hypothyroid.

Table 5: Comorbidities of patients

COMORBIDITIES	No. of cases	Percentage
DM	4	20.0%
HYPERTENSION	5	25.0%
HYPOTHYROID	1	5.0%
NONE	10	50.0%
Total	20	100.0%

Figure 5: Comorbidities of patients



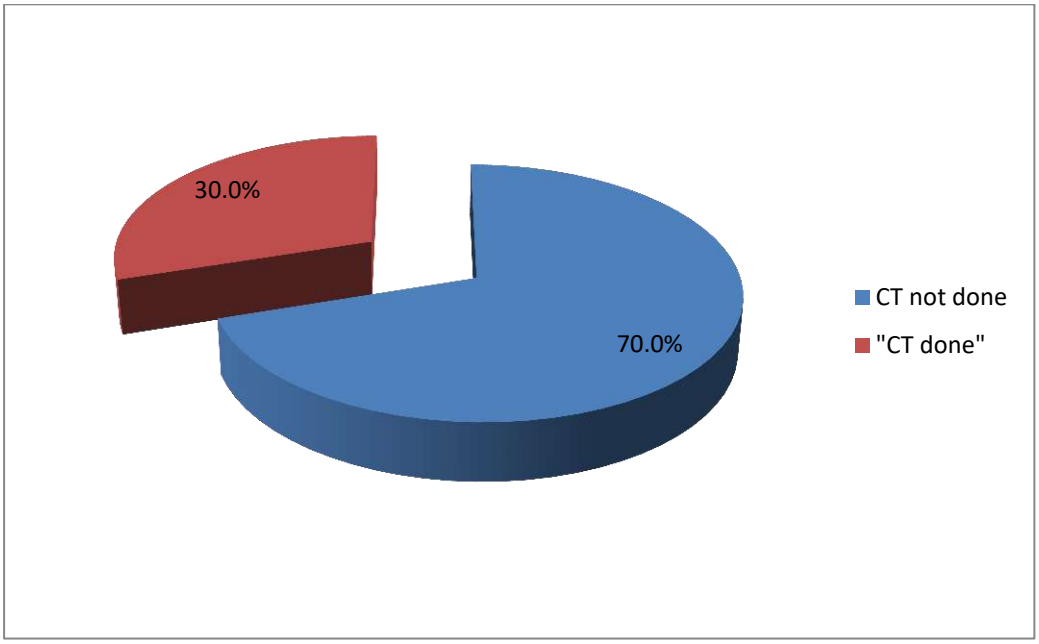
Investigations

USG neck was done in all patients. Every patient had localization performed with Sestamibi scan. Only one patient required CT neck and upper chest.

Table 6: Patients in whom CECT neck and upper chest was done

CECT NECK AND UPPER CHEST	No. of cases	Percentage
CT not done	14	70.0%
"CT done"	6	30.0%
Total	20	100.0%

Figure 6: Patients in whom CECT neck and upper chest was done



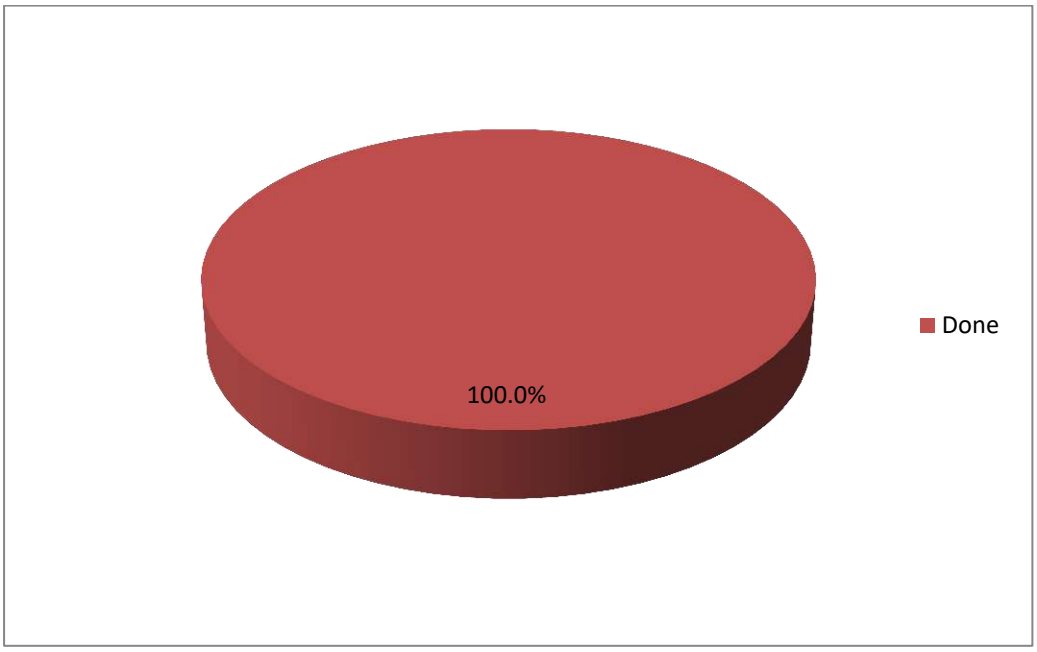
Intra-operative localisation

IOPTH monitoring was used in all patients. Of the 20 patients, frozen section was done in all.

Table 7:Patients in whom intraoperative frozen section was done

FROZEN SECTION	No. of cases	Percentage
Not done	0	0.0%
Done	20	100.0%
Total	20	100.0%

Figure 7: Patients in whom intraoperative frozen section was done



Complications

Significant hypocalcemia – defined as serum Ca <7 mg/dl did occur in two patients, under the syndromic complex of hungry bone syndrome.

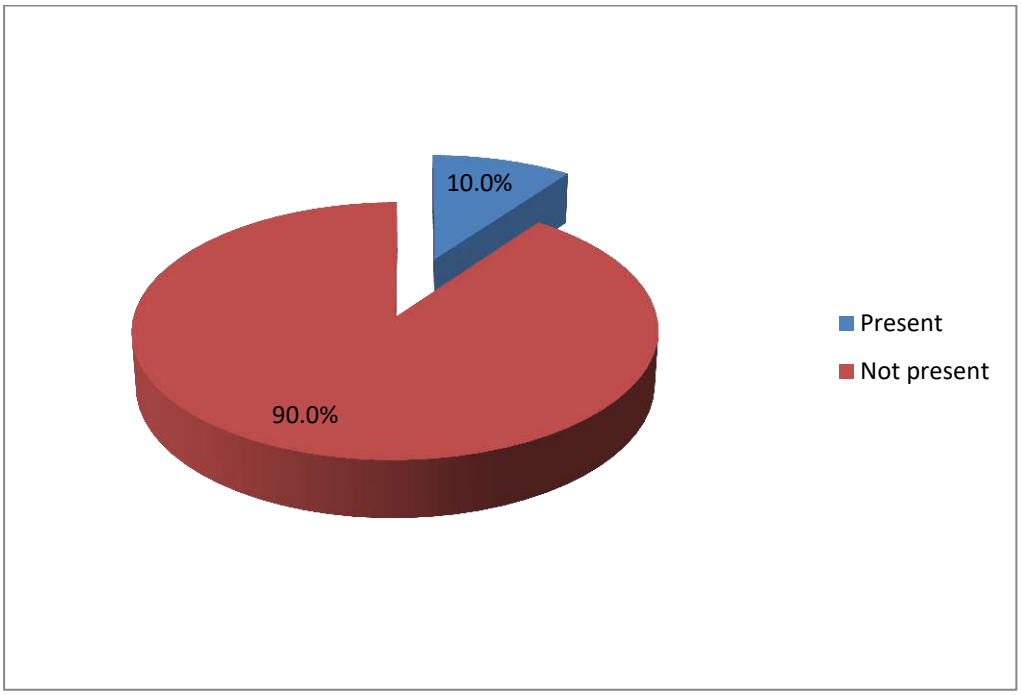
Voice change – seen in none of the patient.

Hungry bone syndrome – seen in 10% patients.

Table 8: Patients developing hungry bone syndrome

HUNGRY BONE SYNDROME	No. of cases	Percentage
Present	2	10.0%
Not present	18	90.0%
Total	20	100.0%

Figure 8: Patients developing hungry bone syndrome

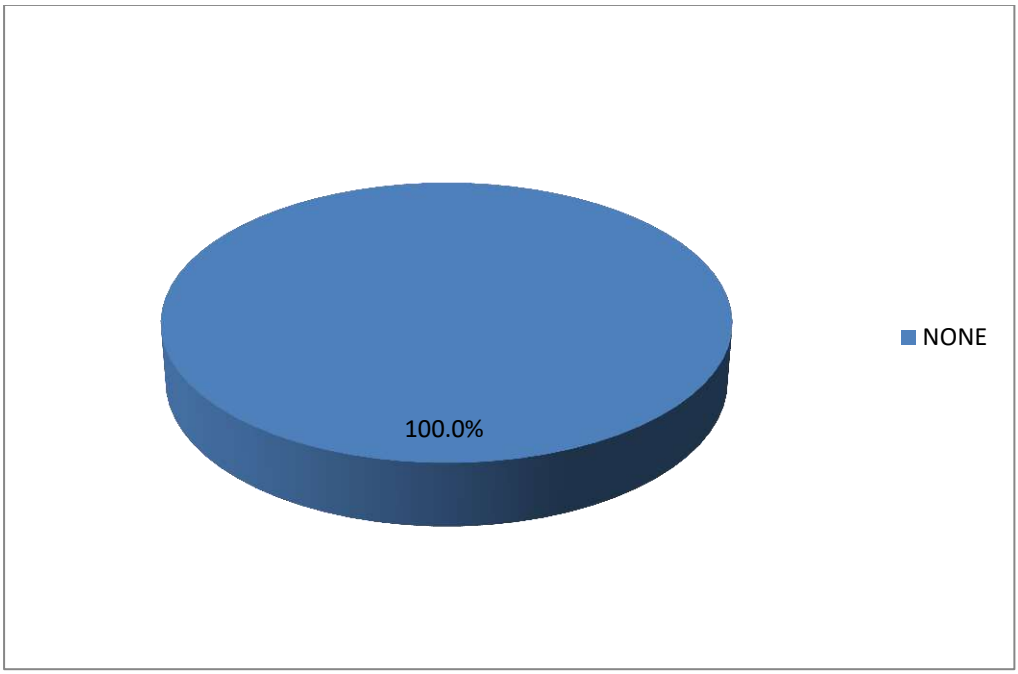


Failure of surgery/recurrence – seen in none

Table 9: Patients who developed recurrence of adenoma

FAILURE/RECURRENCE	No. of cases	Percentage
NONE	20	100.0%

Figure 9: Patients who developed recurrence of adenoma



DISCUSSION

Amongst endocrinological disorders,primary hyperparathyroidism is one of the most common.It's incidence is 1/500 females and 1/2000 males, with post-menopausal women in the age group of 50-60 being involved more commonly[1].

Open parathyroidectomy has traditionally been the standard surgical approach for primary hyperparathyroidism. Initially, this procedure involved bilateral exploration, during which all parathyroid glands were assessed to locate any adenomas. However, technological advancements, such as intraoperative parathyroid hormone (PTH) monitoring and radionuclide imaging, have rendered bilateral exploration largely unnecessary. With the rise of minimally invasive surgical techniques, it is logical to seek advancements in parathyroidectomy methods. Therefore, we conducted this study to evaluate the feasibility of trans-axillary endoscopic parathyroidectomy as a treatment option for primary hyperparathyroidism.

This study was conducted over a period of 3 years, and was prospective and retrospective by design. There was no specific inclusion or exclusion criteria for the patients; all patients who were diagnosed to have PHPT due to parathyroid adenoma and were consenting for surgery were included.

After taking informed consent, these patients were planned for surgery. The possibility of conversion of procedure to open was explained to all patients. Patients were prepared for surgery by medically managing their hypercalcemia; surgery was carried out only when the calcium levels were <10 mg/dl.

Trans-axillary endoscopic parathyroidectomy proceeded through its steps; surgery concluded when IOPTH, and in certain cases frozen section, confirmed excision of adenoma. In the post-op, calcium levels were monitored on POD1 and POD2.

We carried out our study and studied how the following parameters differed from the studies performed earlier.

Age – PHPT is primarily diagnosed in the middle age, with usual patients belonging to the menopausal and peri-menopausal age[45]

Saito et al.	54 years
Zhang et al.	41 years
Burhan Mayir et al.	47.3 years
Kandil et al.	55.6 years
Lee et al.	44.5 years
Sabuneuglu et al.	49.9 years
Current study	42 years

PTH – George L. Irvin III, in the University of Miami developed the initial protocol for parathyroidectomy, called the “Miami protocol”. It required a >50% drop in PTH levels, 10 mins after resection of hyper-functioning tissue to predict removal of adenoma and achievement of post-operative eucalcemia. There are certain modifications of this criteria, which vary from centre to centre.

In our institute, 4mL of whole blood was collected in EDTA vials at the following points:

a) Pre-incision level – before skin incision is given
b) Pre-excision level – collected after dissection and just before clamping the abnormal gland’s blood supply
c) 5-min post excision
d) 10-min post excision

Mean pre-op PTH was 353.17 pg/ml, with the maximum being 1995 pg/ml. Mean pre-incision PTH was 477.2 pg/ml. Mean pre-excision PTH was 430.3 pg/ml. At 5-min post excision, the mean PTH levels were 150.55 pg/ml, and at 10-mins post-excision, the mean was 77.32 pg/ml.

Table 10: PTH levels of patients at various time points

	N	Mean	SD	Minimum	Maximum	Percentiles		
	Valid					25	50	75
PREINCISION (AT INDUCTION OF ANESTHESIA)	20	477.72	584.54	35.00	1995.00	186.95	245.00	323.90
PREEXCISION (AFTER COMPLETE DISSECTION, BEFORE LIGATION OF VEIN/PEDICLE)	20	430.31	671.43	41.69	2859.00	116.78	176.20	449.25
POSTEXCISION- AT 5 MINS	20	150.55	148.92	21.27	641.00	72.00	105.85	186.78
POSTEXCISION- 10 MINS	20	77.32	74.15	12.00	267.00	27.36	51.26	85.80

Various studies had different mean pre-op PTH levels.

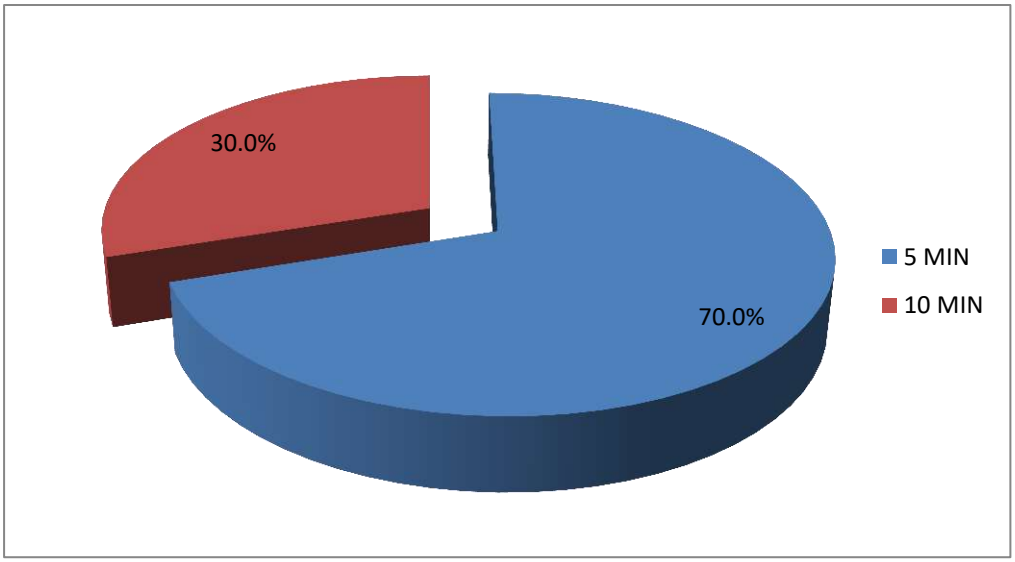
Saito et al.	133 pg/dl
Zhang et al.	225.4 pg/dl
Burhan Mayir et al.	250 pg/dl
Current study	353.17 pg/dl

In accordance with the protocol, we calculated >50% drop in PTH during this serial intra-op monitoring, and surgery was concluded when this drop was achieved. What we discovered was that in 70% of patients, this fall in PTH was achieved within 5-mins of dissection, and in rest, it was achieved at the 10 min mark. This was statistically significant($p < 0.013$ for 5 min mark and $p < 0.003$ for 10 min mark). This led to quicker conclusion of surgery.

Table 11: Patients achieving more than 50% fall in PTH at 5 minutes and 10 minutes

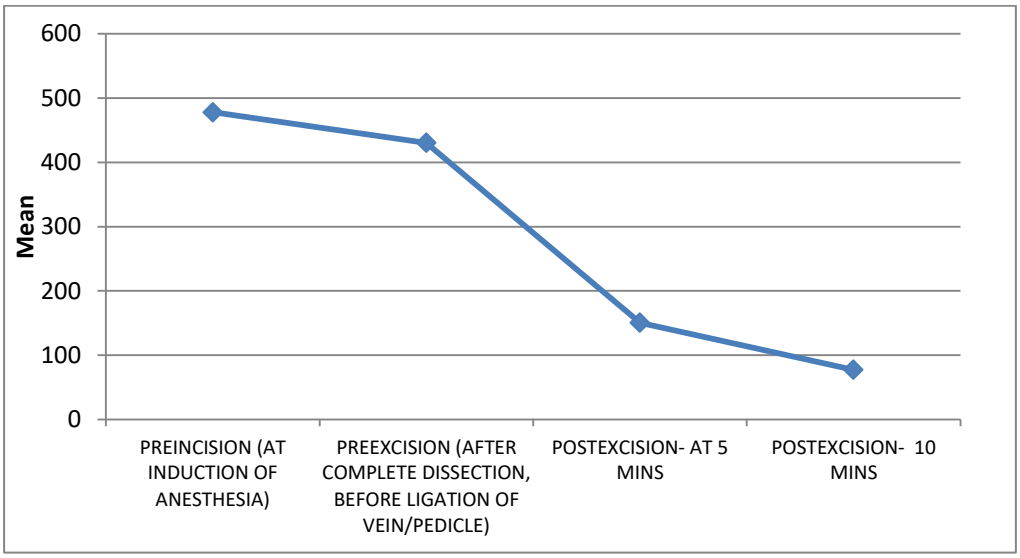
EXCISION FALL MORE THAN 50%	No. of cases	Percentage
5 MIN	14	70.0%
10 MIN	6	30.0%
Total	20	100.0%

Figure 10: Patients achieving more than 50% fall in PTH at 5 minutes and 10 minutes



Overall, our patients demonstrated a serial fall in PTH levels, as calculated by post-excision PTH assay's

Figure 11: Graphical representation of gradual decline in PTH levels



Calcium – mean presenting calcium of our patients was 12.19 mg/dl, with the minimum level being 8.80 mg/dl and maximum being 19 mg/dl. Calcium levels will normalise once the stimulus for calcium excretion, i.e., parathyroid adenoma is removed. Different studies and their mean presenting calcium levels are

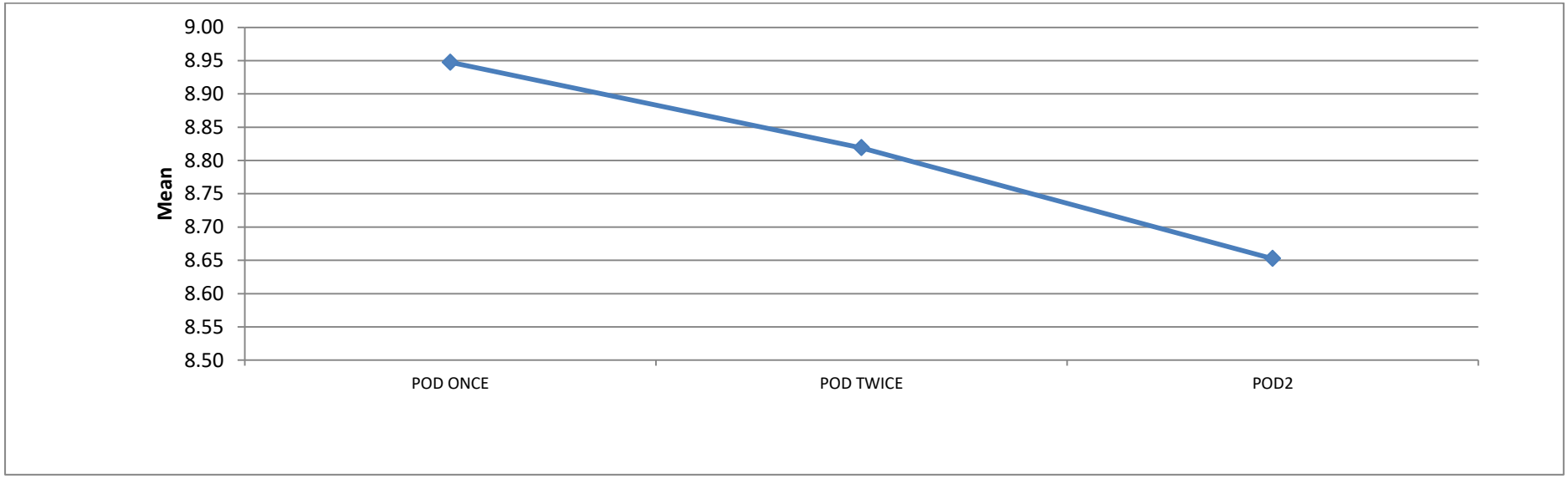
Zhang et al	10.9 mg/dl
Saito et al	11 mg/dl
Burhan Mayir et al	11.5 mg/dl
Our study	12.19 mg/dl

In the post op period, serum calcium levels were calculated on POD1 and POD2. Similar downward trend was noticed in these values too.

Table 12: Post op Calcium levels

	Mean	SD	t	p-value	Difference			95% Confidence Interval of the Difference	
					Mean	Std. Deviation	Std. Error Mean	Lower	Upper
POD ONCE	8.95	1.00							
POD TWICE	8.82	1.04	0.957	0.350	0.13	0.60	0.13	-0.15	0.41
POD2	8.65	0.87	1.922	0.070	0.30	0.69	0.15	-0.03	0.62

Figure 12: Trend of fall in Post op calcium levels



Significant hypocalcemia – drop in calcium levels below 7 mg/dl with associated manifestations such as tingling sensation in peripheries, muscle spasms, seizures, etc is termed significant hypocalcemia. It is usually seen after removal of parathyroids with high pre-op PTH levels. Two of our patient's developed symptomatic hypocalcemia, and as will be discussed ahead, they went on to develop the entire "Hungry bone syndrome". Their hypocalcemia became symptomatic on POD3. It was managed conservatively and patient's eventually recovered.

Hungry bone syndrome – this consists of hypocalcemia, hypomagnesemia, hypophosphatemia. Once a hyperfunctioning parathyroid adenoma is removed, bone forming osteoblasts come into picture; they stimulate bone formation, due to which, there is bony accumulation of calcium, magnesium and phosphorous. Two of our patients developed this complication, but the reason for this was, as mentioned earlier, large parathyroid adenomas with high PTH levels. These patients responded to conservative management.

Recurrent laryngeal nerve – RLN has a close relationship with parathyroid gland, and is at risk of injury during surgery of thyroid and parathyroid. It can be transient or permanent; rates of permanent RLN injury following parathyroidectomy are lower than that following thyroidectomy(0.3% vs 1%). RLN injury manifests as hoarseness of voice. Patients were explained about this possibility, and appropriate consent was taken. None of the patients developed this complication. Patients who developed this complication in various studies is as follows:

Zhang et al	None
Bhandarwar et al	1
Zheng et al	None
Saito et al	None
Burhan Mayir et al	None
Our study	None

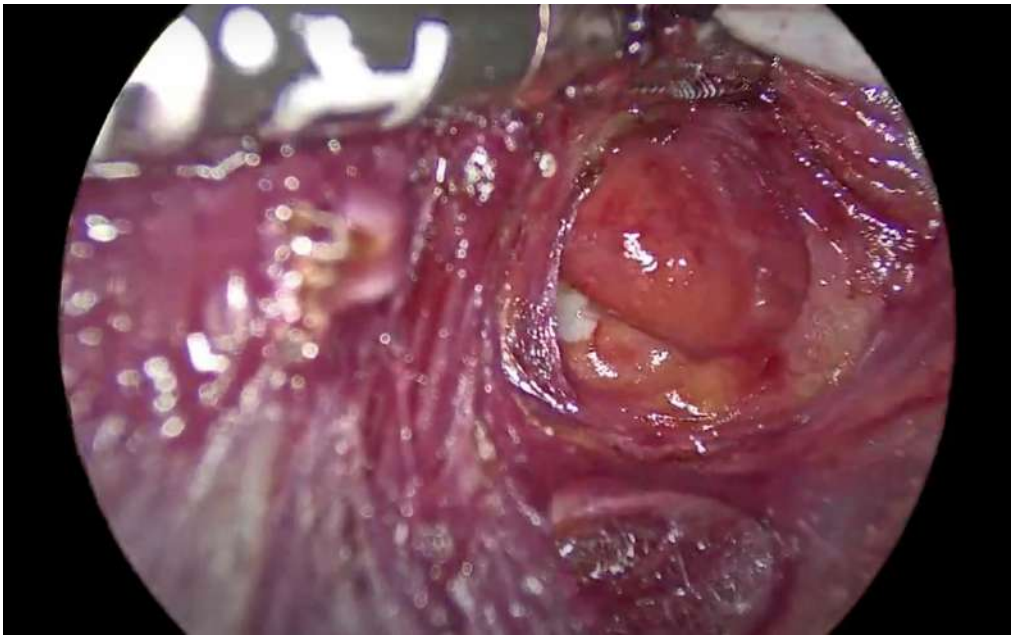
Failure of surgery – failure of endoscopic removal of parathyroids and the need for conversion to open surgery was explained to patients. None of the patients required this, and all parathyroids were excised laparoscopically. In the study by Bhandwar et al, a single patient required conversion to open parathyroidectomy because of unsatisfactory fall in PTH.

Our study has concluded that transaxillary endoscopic parathyroidectomy is chosen by younger populace, with the ends of spectrum of age lying between 12 years and 75 years. When surgery was planned, localization studies were performed in all of our patients; USG neck and Sestamibi scan was performed in all, with 6 patient's requiring CT neck due to inconclusive results of the other two scans. Comorbidities were present in half of our patients, with the most common and second most common being hypertension and diabetes mellitus. As has been proven, these comorbidities had no bearing on end results, with the patients achieving eucalcemic status irrespective of their comorbidities. In 70% of patients, the desired >50% fall in PTH was achieved within 5 mins of adenoma excision, and this was statistically significant($p<0.013$). As this occurred, end point of surgery was achieved. Eucalcemia occurred on POD1 and was maintained on POD2. Even large adenomas were removed laparoscopically, with none of the patients requiring conversion to open. All patients had scar satisfaction; the scar was compatible, especially in case of young patients, with the cosmetic requirements of our patients. Once we proceed with minimally invasive approach in any surgery, the results have translated in the form of shorter hospital stay and earlier discharge. This was seen in our study too; most of the patients were discharged by POD3, baring the two who had developed significant hypocalcemia.

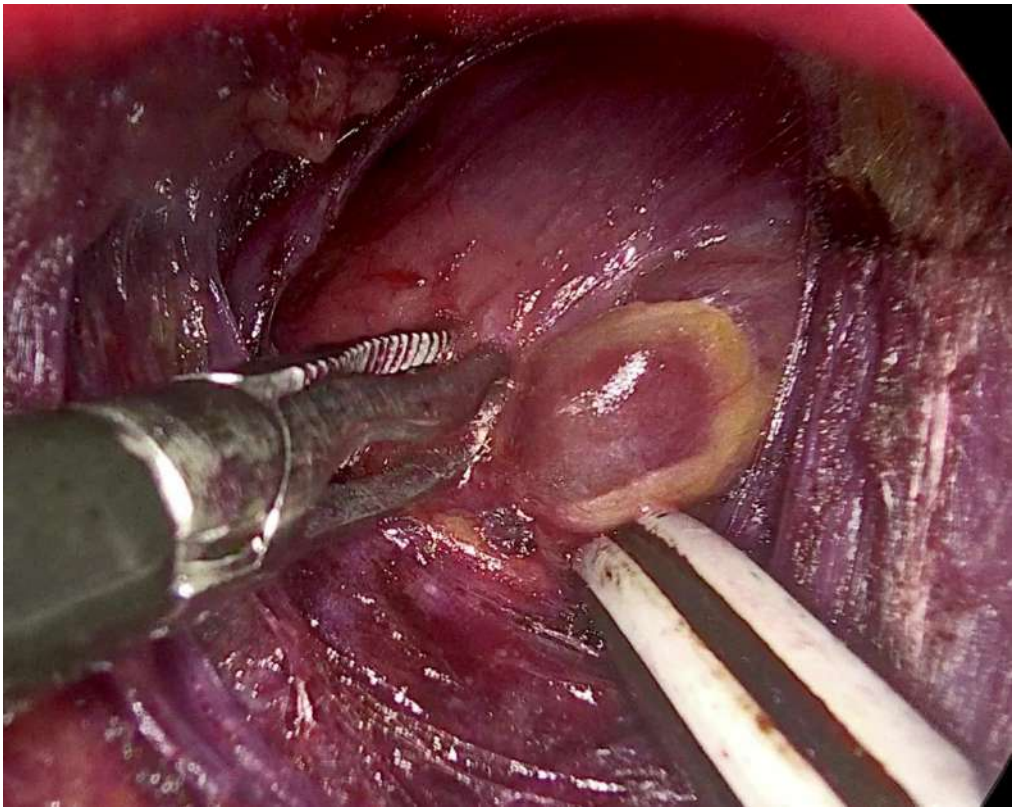
SUMMARY AND CONCLUSION

Our study was prospective and retrospective by design. It was performed over a period of 3 years and included 20 patients with primary hyperparathyroidism secondary to parathyroid adenoma who had opted for parathyroidectomy by trans-axillary endoscopic approach. The surgery was performed after taking informed consent. A diagnosis of PHPT was made by a combination of lab tests and imaging studies, with the latter also localizing the tumor. After getting all the desired clearances, surgery was performed. Intraoperative landmarks like serial PTH monitoring to achieve >50% drop in PTH were carried out, and a pathological evidence of parathyroid tissue by intra-operative frozen section was done. When both IOPTH had a documented fall of >50% from the highest pre-operative value, along with a frozen section positive for parathyroid tissue, the end point for surgery was achieved. We conclude that –

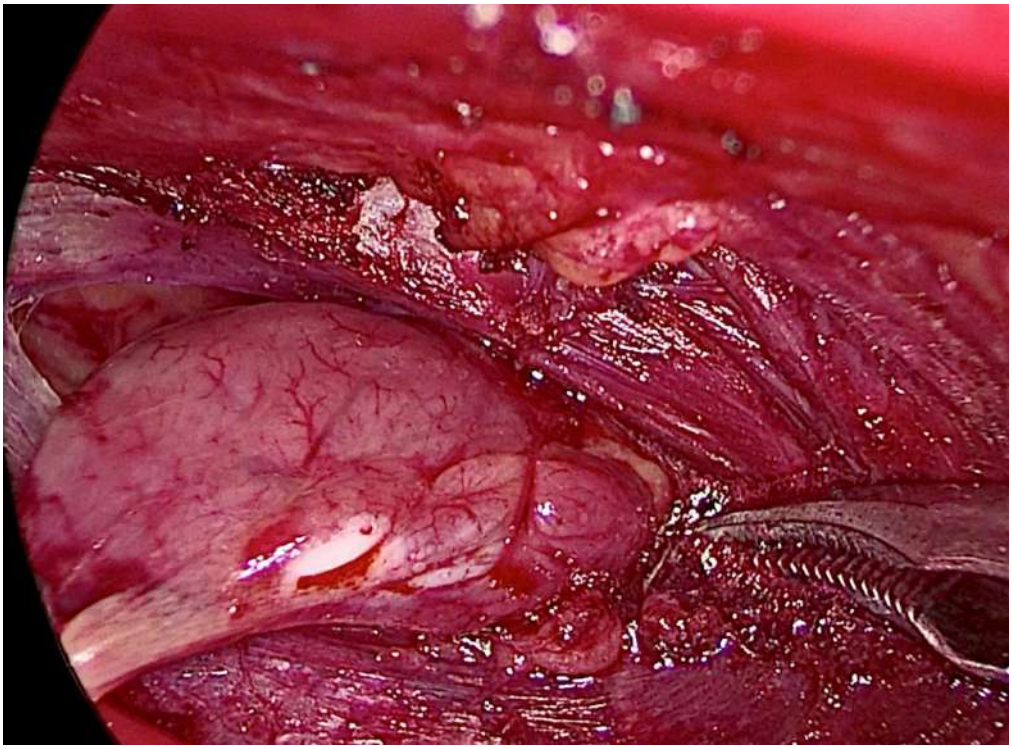
- PHPT is primarily a disease affecting females in the 4^{th}-6^{th} decade of life; as we found out, 80% of our patients were females, and 65% of patients belonging to this age group
- Preoperative imaging is must, as it provides us an evidence of adenoma and localizes the disease as well.
- Endoscope provides better magnification and view of surgical field.
- The enhanced view allows for better dissection of surgical field and more accurate access to the adenoma.
- There is a quicker identification and excision of adenoma, as evidenced by the >50% drop in PTH achieved at 5-min post-excision mark in 70% of patients, and in the rest at 10-min post-excision.
- None of the patients required conversion to open
- None of the patients had recurrence of tumor or failure to excise the tumor
- Patients admit to scar satisfaction



Picture 14: Parathyroid adenoma lying in situ



Picture 15: Excision of parathyroid adenoma



Picture 16: Excised parathyroid adenoma

Picture 17: Saline dip test – done to differentiate parathyroid tissue from fat. If it floats, its fat. If it sinks, its parathyroid.

Picture 18: Scar of transaxillary endoscopic parathyroidectomy – axillary scar provides cosmetic satisfaction.

Thus, transaxillary endoscopic parathyroidectomy is a better treatment option for PHPT secondary to parathyroid adenoma.

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SR. NO.	MRD NO	Initials	AGE	SEX	CHIEF COMPLAINTS	COMORBIDITIES	BP		HR	SPO2	RR	HIGH RESOLUTION USG NECK
1	4348	A	47	FEMALE	CHEST PAIN	NONE	120	80	78	98	20	"+"
2	908068	AS	24	FEMALE	INCIDENTLY DETECTED DURING WORK FOR PCOS	NONE	110	70	86	97	20	"+"
3	1146563	HK	45	FEMALE	PAIN IN FLANK REGION	NONE	130	80	80	97	16	"+"
4	1144711	JS	67	MALE	PAIN LOWER BACK, FACIAL SWELLING	HYPERTENSION	150	80	70	95	18	"+"
5	1243540	KK	60	FEMALE	PAIN ABDOMEN	DM	130	80	66	98	20	"+"
6	986157	SR	63	FEMALE	FEVER WITH ALTERED SENSORIUM	DM	130	80	104	94	20	"+"
7	1313272	RS	75	MALE	T2 DM, HTN	T2DM	220	80	80	94	20	"+"
8	481154	LMS	61	MALE	JOINT PAINS	HYPERTENSION	140	90	74	96	20	"+"
9	1482015	SG	39	FEMALE	BACK PAIN	NONE	130	80	80	97	18	"+"
10	1740400	NA	25	FEMALE	PAIN ABDOMEN	NONE	140	90	95	98	19	"+"
11	1699627	PA	49	FEMALE	PAIN ABDOMEN	HYPOTHYROID	130	80	85	97	18	"+"
12	1703963	BK	61	FEMALE	ALTERED SENSORIUM	HYPERTENSION	110	70	70	96	16	"+"
13	1707105	MK	55	FEMALE	ALTERED SENSORIUM	DM	130	85	90	97	17	"+"
14	546986	P	39	FEMALE	PAIN ABDOMEN	NONE	120	80	82	98	19	"+"
15	1426463	PR	67	FEMALE	PAIN ABDOMEN	NONE	125	80	85	99	20	"+"
16	1359934	SK	43	FEMALE	FLANK PAIN	NONE	130	70	75	98	19	"+"
17	1701483	SB	68	FEMALE	PAIN ABDOMEN	HYPERTENSION	120	80	72	96	18	"+"
18	1308840	JS	58	FEMALE	FLANK PAIN	HYPERTENSION	115	70	70	98	18	"+"
19	358726	KJ	26	FEMALE	PAIN ABDOMEN	NONE	130	85	80	98	17	"+"
20	1750549	RSJ	12	MALE	PAIN IN BOTH FEET	NONE	140	90	85	99	18	"+"

SR. NO.	MRD NO	Initials	CECT NECK AND UPPER CHEST	SESTAMIBI SCAN	S. PTH	S. CALCIUM	S. PHOSPHATE	S. ALP	RFT	PREINCISION (AT INDUCTION OF ANESTHESIA)	PREEXCISION (AFTER COMPLETE DISSECTION, BEFORE LIGATION OF VEIN/PEDICLE)
1	4348	A	-	"+"	169.6	11.3	1.9	141	0.74	271	375
2	908068	AS	"+"	"+"	123.6	11	2.5	88	0.6	241	132
3	1146563	HK	-	"+"	192	11.4	2.9	127	0.6	271	273
4	1144711	JS	-	"+"	233	11.4	3	111	1.9	249	231
5	1243540	KK	-	"+"	152.9	11.3	2	152	0.78	323	199
6	986157	SR	-	"+"	290	11.8	2	176	0.41	290	308
7	1313272	RS	-	"+"	35	11.6	1	76	0.9	35	56.37
8	481154	LMS	"+"	"+"	1381	16.1	2.6	100	1.58	1060	474
9	1482015	SG	"+"	"+"	112	11.4	3	73	0.48	112	152
10	1740400	NA	-	"+"	169.1	11.3	2.5	109	0.62	198.7	142.7
11	1699627	PA	"+"	"+"	75.87	8.9	2.9	58	0.7	56.87	61.49
12	1703963	BK	-	"+"	90.99	10.8	2.07	147	1.1	193.7	153.4
13	1707105	MK	-	"+"	1995	19	2.3	141	2.13	1995	2859
14	546986	P	-	"+"	817.2	11.4	1.5	1037	0.48	1921	1632
15	1426463	PR	-	"+"	175.9	12.1	3	76	0.91	234.8	111.7
16	1359934	SK	"+"	"+"	281.3	15.5	1.72	157	1.38	222.5	145.1
17	1701483	SB	-	"+"	167.8	8.8	1.9	140	1.17	184.7	105.3
18	1308840	JS	-	"+"	111.7	10.3	1.46	112	0.71	324.2	554.9
19	358726	KJ	"+"	"+"	171.9	11.4	2	153	0.62	171	41.69
20	1750549	RSJ	-	"+"	317.6	16.9	2.4	148	0.9	1200	598.6

SR. NO.	MRD NO	Initials	POSTEXCISION-AT 5 MINS	POSTEXCISION-10 MINS	FROZEN SECTION	POD ONCE	POD TWICE	POD2	SIGNIFICANT HYPOCALCEMIA	VOICE CHANGES	HUNGRY BONE SYNDROME	FAILURE/ RECURRENCE
1	4348	A	641	65.82	"+"	8.5	7.8	8	NONE	NONE	NONE	NONE
2	908068	AS	38	23	"+"	7.8	8.3	8.3	NONE	NONE	NONE	NONE
3	1146563	HK	72	44	"+"	8.9	9.1	8.7	NONE	NONE	NONE	NONE
4	1144711	JS	111	57	"+"	10	9.4	8.7	NONE	NONE	NONE	NONE
5	1243540	KK	72	40	"+"	8.2	8.3	8	NONE	NONE	NONE	NONE
6	986157	SR	117	12	"+"	8.6	8.5	8.5	NONE	NONE	NONE	NONE
7	1313272	RS	22.07	12	"+"	8.3	8.8	8.6	NONE	NONE	NONE	NONE
8	481154	LMS	348	267	"+"	9.9	9.1	9.4	NONE	NONE	NONE	NONE
9	1482015	SG	131	38	"+"	8.3	8.2	8.4	NONE	NONE	NONE	NONE
10	1740400	NA	106.6	78.9	"+"	11.07	10.86	10.55	NONE	NONE	NONE	NONE
11	1699627	PA	21.27	12.72	"+"	9.23	8.08	8.8	NONE	NONE	NONE	NONE
12	1703963	BK	105.1	55.55	"+"	9.79	10.82	10.73	NONE	NONE	NONE	NONE
13	1707105	MK	332	223	"+"	7.6	7.74	7.36	"+"	NONE	"+"	NONE
14	546986	P	258	202	"+"	8.7	7.3	7.8	NONE	NONE	NONE	NONE
15	1426463	PR	74.59	46.66	"+"	8.8	8.9	9.21	NONE	NONE	NONE	NONE
16	1359934	SK	85.16	56.82	"+"	10.6	10.1	8.6	NONE	NONE	NONE	NONE
17	1701483	SB	82.36	46.96	"+"	9.4	9.2	9	NONE	NONE	NONE	NONE
18	1308840	JS	175.9	153	"+"	7	7	7.5	NONE	NONE	NONE	NONE
19	358726	KJ	27.56	23.81	"+"	9	9.64	7.9	NONE	NONE	NONE	NONE
20	1750549	RSJ	190.4	88.1	"+"	9.26	9.24	9	"+"	NONE	"+"	NONE

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The Principal
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Subject:: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 25.09.2023 has approved the plan of thesis of **Ravneet Singh Randhawa**, a student of your college for **MS General Surgery** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Role of transaxillary endoscopic parathyroidectomy in primary hyperparathyroidism due to parathyroid adenoma .

Supervisor
Dr. Atul Mishra
Professor
Dept. of General Surgery

Co-Supervisor:-
Dr. Saurabh Arora
Asst. Professor
Dept. of Endocrinology

Co-Supervisor:-
Dr. Amandeep Singh Nair
Asst. Professor
Dept. Of General Surgery

The student may submit the thesis in triplicate alongwith the plan in triplicate also, to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She may be directed to attach a photocopy of this letter with the forwarding letter while submitting thesis in the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic, if any.

Controller of Examinations

Note :

1. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTER OF SURGERY

IN

GENERAL SURGERY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES
FARIDKOT

AUGUST, 2022

DR. RAVNEET SINGH RANDHAWA

DEPARTMENT OF GENERAL SURGERY
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ABSTRACT OF PLAN OF THESIS

Title	ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA
For the degree of	MS General Surgery
Name of the candidate	Dr. Ravneet Singh Randhawa
Supervisor	Dr. Atul Mishra, Professor, Department of General Surgery, DMCH, Ludhiana.
Co-Supervisor	Dr. Saurabh Arora, Assistant Professor, Department of Endocrinology, DMCH, Ludhiana Dr. Amandeep Singh Nar, Associate Professor, Department of General Surgery, DMCH, Ludhiana.
Institution	Dayanand Medical College and Hospital,Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction:85% of patients with primary hyperparathyroidism have a single adenoma." Minimally invasive parathyroidectomy", which is parathyroidectomy with limited exploration has replaced cervical exploration for most patients with parathyroid adenoma. MIP is better than cervical exploration better in terms of complication rate, operation time, length of hospital stays, cost, cosmetic outcome.

Aim of Study: To evaluate trans axillary endoscopic parathyroidectomy as an option for primary hyperparathyroidism secondary to parathyroid adenoma.

Materials& methods: A retrospective and prospective study of patients with primary hyperparathyroidism, undergoing trans axillary parathyroidectomy in the department of General Surgery, Dayanand medical college and hospital, over a period of one year.

Clinical Significance: As an alternative treatment option for parathyroid adenoma with lesser rate of complications as compared to open parathyroidectomy.

Keywords: Transaxillary endoscopic parathyroidectomy, adenoma

(Signature) Candidate	(Signature) Co-supervisor	(Signature) Co-supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA"** exist in the Department of General Surgery at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate himself under our supervision and guidance.

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Place : _____

Date : _____

APPROVAL PROFORMA
BY
RESEARCH & ETHICAL COMMITTEE
DAYANAND MEDICAL COLLEGE & HOSPITAL, LUDHIANA

Name of candidate	Dr. Ravneet Singh Randhawa
Department	General Surgery
Topic of Thesis	ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA
Likely date of appearing in PG examination	May/June 2024
Date of enrollment	2 May, 2022
Name of Head of Department	Dr. Jaspal Singh
1) Supervisor **2) Co-Supervisor**	Dr. Atul Mishra Dr. SaurabhArora Dr. Amandeep Singh Nar
Signature of Members of Research Committee with Stamp	**Signature of Members of Ethics Committee with Stamp**
Dr. Harpreet Kaur (Professor & Head, Pathology)	Mr. R K Sharma (Legal Expert)
Dr. Jaspal Singh (Professor & Head, Surgery)	Dr. RamitMahajan (Associate Professor, Gastroenterology)
Dr. Dinesh Gupta (Professor & Head, Medicine)	Dr. Anu Sharma (Professor, Anatomy)
Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)	Dr. Sandeep Kaushal (Dean Academics & Professor & Head, Pharmacology)
Dr. Gurpreet S Wander (Vice Principal)	Dr. Gurpreet S Wander (Vice Principal & Professor & Head, Cardiology)
	Dr. Gagandeep Singh (Secretary, Ethics Committee Professor & Head, Neurology)

Approved: Yes / ~~No~~

Dr. Sandeep Puri
Chairperson
Research Committee
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Research Committee

Approved: Yes / ~~No~~

Prof. Arvind Malhotra
Chairperson
Ethics Committee
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BABA FARID UNIVERSITY OF HEALTH SCIENCES, FARIDKOT

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1	NAME OF THE CANDIDATE AND ADDRESS	DR. RAVNEET SINGH RANDHAWA 96 GUJRAL NAGAR, JALANDHAR, PUNJAB. PIN 144001
2	NAME OF THE INSTITUTE	Dayanand Medical College & Hospital, Ludhiana
3	COURSE OF STUDY AND SUBJECT	MS General Surgery
4	DATE OF ADMISSION OF COURSE	2 May, 2022
5	TITLE OF THE TOPIC	ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Primary hyperparathyroidism is the third most common endocrine disorder. Hyperparathyroidism is of three major types(Primary, Secondary and Tertiary) with primary hyperparathyroidism being the most common cause of hypercalcemia in adults. Adenoma is the most common cause of primary hyperparathyroidism with an incidence of 1 in 500 in females and 1 in 2000 in males). It mostly affects postmenopausal women in the age group of 50-60 years. Most cases of parathyroid adenoma are sporadic with syndromes(e.g.,MEN syndromes) accounting for only 3-5% of cases. Other causes of primary hyperparathyroidism(parathyroid hyperplasia, parathyroid carcinoma) accounting for only a minority of cases. Diagnosis of primary hyperparathyroidism is usually incidental in 80% of cases. Patient can present with any or all of the following features –

- Nephrolithiasis(recurrent)
- Polyuria
- Polydipsia
- Non traumatic fractures
- Osteoporosis(m.c affects distal 1/3rd of radius)
- Bone pain
- Muscle weakness(proximal)
- Muscular atrophy
- Easy fatiguability
- Gastroesophageal reflux
- Constipation
- Pain abdomen
- Peptic ulcers
- Acute pancreatitis
- Depression
- Emotional lability
- Difficulty in concentration
- Heart block

The only curative treatment for primary hyperparathyroidism is surgery. Two major surgical approaches to parathyroidectomy are traditional open approach (transverse cervical incision) and minimally invasive endoscopic technique.

Open cervical approach - easy to explore the bilateral cervix because it provides direct access to the gland. This is usually preferred when

- Pathological parathyroid gland could not be identified preoperatively
- The coexistent thyroid gland requires surgery
- Multigland disease is suspected
- Pathological parathyroid is large in size
- Secondary and tertiary hyperparathyroidism

Multigland disease is defined as persistently elevated IOPTH despite removal of pathological parathyroid. Incidence is variable.
However, open cervical parathyroidectomy has multiple complications such as postoperative seroma formation due to wider dissection area used and it has a big disfiguring scar on most exposed area of body, that is, neck.

Transaxillary approach provides better visual field than open as it offers better magnified view which enables careful dissection and further decreasing the complications. Also, it has a small, more cosmetic scar because it's a minimal invasive approach in which a very small incision is required, thus a cosmetically superior alternative to cervical pararthyroidectomy which conceals the lesion within the axilla. As compared to traditional approach, this surgical technique has less chances of postoperative seroma formation and reduced rate of complications.[1-4] MIP provides the inherent benefit of magnifying local anatomy, hence a higher rate of removal of target parathyroid gland.[2,5,6] There is superior visualization of recurrent laryngeal nerve.[7-10] hence lesser risk of Recurrent laryngeal nerve palsy.[8-12]

Studies done on paediatric patients with primary hyperparathyroidism has found MIP to be superior to BNE in terms of post of calcium levels,fall in PTH levels,recurrence.[7,13,14]

Targeted parathyroidectomy, when appropriately selected and carried out, is an effective treatment of primary hyperparathyroidism in most cases. Intraoperative rPTH can correctly guide removal of hyperfunctioning glands. Targeted parathyroidectomy offers the advantage of less invasive surgery with less tissue dissection confined to one side and avoids surgically disturbing the remainder of the neck. This should reduce postoperative complications and allow for easier and safer re-exploration in the few cases with persistent or recurrent disease.[15]

6.2 REVIEW OF LITERATURE

Oscar Vidal-Perez, Mauro Valentini, Julan Carlos Baanante-Cerdena, Cesar Ginesta-Marti, Laureano Fernandez-Cruz, Juan Carlos Garcia-Valdecasas did a prospective study conducted between April 2010 and April 2013. A total of 28 endoscopic lateral parathyroidectomies were performed I among patients who were diagnosed with sporadic primary hyperthyroidism. Postoperative morbidity was compared to that reported in the classical approach. A favorable outcome was observed in 27 of the 28 patients after a mean follow up of 22 months.[1]

Yoshiyuki Saito, Yoshifumi Ikeda, Hiroshi Katoh, Atsushi Nakao. Hiroshi Takami in 2020 retrospectively compared the surgical outcomes of TEP and open minimally invasive parathyroidectomy (MIP) analyzed 28 patients with primary hyperparathyroidism and concluded that TEP is a good surgical procedure for hyperparathyroidism caused by single adenoma, and it achieves superior cosmetic results without increasing the rate of complications.[2]

Ciaran WP Kelly, Chee-Yean Eng and M Shahed Quraishi did a retrospective review of patients who underwent MIP for pHPT due to solitary parathyroid adenoma from April 2006 to August 2012. All patients were initially investigated by endocrinologist to confirm pHPT with pre-op USG scan and Sestamibi scan. One hundred fifty consecutive patients were included with a median age of 62 years. Preoperative USG and Sestamibi scans were concordant in 71% cases. In combined modality(USG and Sestamibi), localisation was 94.8% accurate. There was 95.5% identification of parathyroid tissue confirmed by intraoperative frozen section.[3]

W Wong, F J Foo, M I Lau, A Sarin and P Kiruparan did a prospective study of first one hundred patients undergoing minimally invasive parathyroidectomy(MIP) by a single surgeon at a single institution were included. Preoperatively, patients underwent US and Sestamibi scan for localisation. Parathyroidectomy was performed following an

algorithm of intraoperative decisions. Serum calcium and/or parathyroid hormone levels were checked at follow up. Postoperative normocalcemia was considered success independent of serum parathyroid levels. Patients had a median age of 63 years. Of the 100 patients, 83 were female and 17 were male. Seven patients had a conversion to bilateral neck exploration. The mean operative time for unilateral and bilateral exploration was 42.38 minutes and 76.43 minutes respectively. Separately, a MIBI scan and US lateralised the side of lesion in 82.8% and 79.5% cases, respectively. When a US and MIBI scan agreed, the predictive accuracy of the side of the lesion was 87.5%. The majority of patients(96%) had a successful return to normocalcemia. No complications were encountered.[4]

Hany Abdelfatah El-Hady, Hisham Saleh Radwan did a prospective analysis of focused open parathyroidectomy for 20 patients presented to the department of surgery between Oct 2012 and Jan 2015 at the faculty of medicine, Al Azhar University, Cairo, Egypt diagnosed as sporadic hyperparathyroidism with either positive MIBI scan or US were done. In this study, focused minimal access parathyroidectomy was successful in 95% with no major surgical complications, i.e., recurrent laryngeal nerve palsy or permanent hypoparathyroidism. The patient's mean age was 46.5 ± 12 years. The preoperative serum calcium level ranged from 8.8-15.2 mg/dl. The parathyroid hormone level was elevated ranging from 123-2000 pg/mL. In 90% cases, serum levels of alkaline phosphatase were elevated, while serum phosphorous was low with range of 1.5-4.7 mg/dL. The left inferior parathyroid gland was the most commonly involved gland(40%). Using ultrasound and Sestamibi scan for preoperative localization was accurate in 75% and 90%, respectively. When both techniques were combined, localization accuracy increased to 95%.[5]

Amanda M Laird, Steven K Libutti did a statistical analysis of 5 studies involving a total of 323 patients and found MIP to be superior to BNE in

terms of achievement of eucalcemic status, injury to RLN, time of procedure.[6]

Edna E Mancilla 1, Michael A Levine 2, N Scott Adzick – did a retrospective study on 17(11 female and 6 male) patients belonging to paediatric age group who underwent MIP with IOPTH monitoring and found a cure rate of 100% at 6 months post surgery.[7]

Marcin Barczynski 1, Aleksander Konturek, Stanisław Cichon, Alicja Hubalewska-Dydejczyk, Filip Golkowski, Bohdan Huszno – did a study to evaluate effectiveness of MIP combined with IOPTH monitoring and compare bit with BNE without IOPTH monitoring. A total of 177 patients were enrolled and divided into 2 groups(group 1 – BNE without IOPTH monitoring; group 2 – MIP with IOPTH monitoring). Of the group 1 vs. 2 patients, 57/62 (91.9%) vs. 114/115 (99.1%) were cured (P = 0.01). Five (8.1%) of the group 1 patients were hypercalcaemic postoperatively, owing to an additional, overlooked, hyperfunctioning parathyroid gland, whereas among the 115 group 2 patients, 104 (90.4%) underwent resection of a single parathyroid adenoma, met the Miami criterion, and were cured. The remaining 11 (9.6%) patients did not have an adequate reduction in parathyroid hormone levels and underwent further neck exploration, with resection of additional hyperfunctioning parathyroids in nine of them. One group 2 patient was not cured. However, a decrease of less than 50% of intraoperative parathyroid hormone (iPTH) assay correctly identified the risk of persistent disease in that patient. Another patient in group 2 had a false-negative IOPTH result. The value-added accuracy of IOPTH (correct assay-based surgeon's decision of further neck exploration) was demonstrated in 3 of 78 group 2 patients with concordant results of both imaging studies vs. 7 of 37 group 2 patients with only one positive imaging study, or 3.8 vs. 18.9% of patients (P = 0.007).[8]

6.3 AIMS AND OBJECTIVES OF THE STUDY

- To evaluate role of transaxillary endoscopic parathyroidectomy for primary hyperparathyroidism secondary to parathyroid adenoma.

7. MATERIALS AND METHODS

A retrospective (2 years) and prospective(1.5 years) study will be done on all the patients undergoing transaxillary endoscopic parathyroidectomy in DMCH, Ludhiana. Clinical outcome will be assessed on the basis of fall in S.Ca levels, fall in S.PTH levels, resolution of symptoms, development of complications.

7.1 SOURCE OF DATA

A retrospective and prospective study will be done on patients diagnosed with parathyroid adenoma undergoing trans axillary parathyroidectomy in the department of General Surgery Dayanand medical college and hospital, Ludhiana during a 3-year period.

7.2 METHOD OF COLLECTION OF DATA

All patients detected with parathyroid adenoma will be included in study. Consent will be obtained from each patient and relevant detailed history will be elicited. Findings of general physical and systemic examination will be recorded. Before conducting the study, the procedure will be explained to the patient in his/her vernacular language to allay the anxiety and fear.

Inclusion Criterion

All patients diagnosed with primary hyperparathyroidism undergoing trans axillary parathyroidectomy.

Exclusion Criterion

Anyone who is unwilling to participate in the study.

DURATION OF STUDY/ NUMBER OF CASES: One year [mention time period]

OUTCOME: To evaluate the role of transaxillary endoscopic parathyroidectomy in primary hyperparathyroidism due to parathyroid adenoma.

STATISTICAL ANALYSIS: Data will be described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS ? IF SO, PLEASE DESCRIBE BRIEFLY.

This study requires USG neck and Tc-99m scan to be done on patients who present with parathyroid masses and are planned for transaxillary endoscopic parathyroidectomy.

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Attached herewith

8. LIST OF REFERENCES.

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15. Sadeghi N, Akin E, Lee JY, Roland J, Knoll S. Targeted parathyroidectomy: effectiveness and intraoperative rapid-parathormone dynamics. The Laryngoscope. 2008;118:1997-2002.

PROFORMA

SR.NO: MRD NO:

NAME:

S/O/D/O: AGE & SEX:

ADRESS:

PHONE NUMBER:

DOA:

DOD:

CHIEF COMPLAINS:

COMORBIDITIES (IF ANY):

CLINICAL EXAMINATION:

BP:

HR:

SPO2:

RR:

Preoperative tests:

Preoperative imaging

1) High resolution USG neck
2) CECT neck and upper chest
3) Sestamibi scan

Preoperative lab tests

1. S. PTH
2. S. Calcium
3. S. Phosphate
4. S. ALP
5. RFT

Signature of Candidate **Signature of Supervisor**

Preoperative tests

- **Intra-op PTH assay**(Irving/Miami criteria) – intraop PTH levels are measured at following intervals
    - **Preincision(at induction of anesthesia)**
    - **Preexcision(after complete dissection, before ligation of vein/pedicle)**
    - **Postexcision- at 5 mins, 10 mins**

There should be >50% fall in PTH level from highest preexcision value;this signifies >95% chance of removal of all functioning parathyroid gland. If fall is <50%,we will go for bilateral neck exploration

- **Frozen section**

Postoperative tests

- **S. Calcium –** done on POD1(twice) and POD2(once)

Postoperative complications

SIGNIFICANT HYPOCALCEMIA:

VOICE CHANGES:

HUNGRY BONE SYNDROME:

FAILURE/RECURRENCE:

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I…….D/o, W/o, S/o……..…… am willing to participate in the study **"ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

……. ……
Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य "**ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA"** में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____	_____
गवाह के हस्ताक्षर	रोगी के हस्ताक्षर/अंगूठे का निशान
नाम:	नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

“ROLE OF TRANSAXILLARY ENDOSCOPIC PARATHYROIDECTOMY IN PRIMARY HYPERPARATHYROIDISM DUE TO PARATHYROID ADENOMA” ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ